

Essays

Is There a Design Defect in the *Restatement (Third) of Torts: Products Liability*?

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In the *Restatement (Third) of Torts: Products Liability*, the American Law Institute (ALI) announced a general rule to resolve the problem of the meaning of the word “defect,” a problem that has haunted the law of torts since section 402A of the ALI’s 1965 *Restatement (Second)* ushered in the era of strict liability for defective products. The new rule rejects consumer expectations as a reliable measure of defect and proposes that the key question is whether there existed a feasible alternative safer design, the omission of which was unreasonable.¹ The *Restatement (Third)* thus heralds the end of strict liability for product sellers, grounding products-liability law’s key concept—the defective product—in the law of negligence.

Courts had long grappled with the problem of defining “defect,” drawing on concepts such as warranty and the consumer’s reasonable expectations. But they drew most successfully on risk-utility analysis, a

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1. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998) [hereinafter RESTATEMENT (THIRD)] (“Assessment of a product design in most instances requires a comparison between an alternative design and the product design that caused the injury, undertaken from the viewpoint of a reasonable person. That approach is also used in administering the traditional reasonableness standard in negligence.”). The policy reasons that support use of a reasonable-person perspective in connection with the general negligence standard also support its application to products liability.

negligence-based approach championed by John Wade,² the successor to William Prosser as Reporter for the *Restatement of Torts*. The “alternative-safer-design” rule enshrined in section 2 of the *Restatement (Third)* is the vindication of Wade’s view that design-defect litigation should turn on whether the product could have and should have been made safer before it was sold. Section 2 articulates a functional standard³ that does not depend on the common-law categories that have persisted since the announcement of the *Restatement (Second)*’s section 402A.⁴ In adopting the alternative-safer-design standard, the ALI thus resolved the doctrinal wars of the past thirty-five years over strict-liability, negligence, and warranty theories of liability.

But a design defect lurks in the heart of the *Restatement (Third)*. In section 6(c), the ALI, virtually without debate, adopted a rule that exempts sellers of prescription drugs⁵ and medical

2. Wade offered a list of factors he deemed significant in applying the “unreasonably dangerous” standard:

- (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
- (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
- (3) The availability of a substitute product which would meet the same need and not be as unsafe.
- (4) The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
- (5) The user’s ability to avoid danger by the exercise of care in the use of the product.
- (6) The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
- (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 *MIS. L.J.* 825, 837-38 (1973).

Many courts, including those in New Jersey and California, have derived their risk-utility tests from Wade. *See, e.g., Barker v. Lull Eng’g Co.*, 573 P.2d 443, 455 (Cal. 1978) (adopting the following five factors in its design-defect analysis: the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design); *Cepeda v. Cumberland Eng’g Co.*, 386 A.2d 816, 826-27 (N.J. 1978) (citing Wade’s factors in its design-defect analysis). *But see* James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 *N.Y.U. L. REV.* 1263, 1267 n.9 (1991) (criticizing Wade as the intellectual precursor of the “liability without defect” trend).

3. *See* RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. n (explaining that its rules are stated functionally rather than in terms of traditional doctrinal categories such as warranty, negligence, or strict liability).

4. RESTATEMENT (SECOND) OF TORTS § 402A (1965) [hereinafter RESTATEMENT (SECOND)].

5. The Food, Drug & Cosmetics Act, 21 U.S.C. § 321(g)(1) (1994), defines “drug” broadly to include a biologic product used to diagnose, cure, mitigate, treat, or prevent any disease or to affect the function or structure of the body. Blood and blood products are included in the category of drugs under 21 C.F.R. § 607.3(b) (1998). Vaccines are drugs subject to FDA regulation under 42 U.S.C. § 262 (1994). Some vitamin products are categorized as drugs under 21 U.S.C.

devices⁶ from the alternative-safer-design standard applied to all other products.⁷ Under the ALI's new rule, designers and manufacturers of drugs and medical devices will not be held liable even if their products reasonably could have been made safer. The manufacturer need persuade the factfinder only that, on balance, the product does more good than harm for at least one class of users, so that a reasonable physician would prescribe it. The alternative-safer-design standard is rejected not only for drugs, but also for vaccines and mechanical devices such as cardiac pacemakers. Blood products, although regulated as drugs by the Food and Drug Administration (FDA), are excluded entirely from the *Restatement*, which acquiesces in the wide legislative ban on strict or warranty liability for blood products. The *Restatement (Third)* thus carves out a special, protective standard for a uniquely favored industry.

The two-tiered system that section 6(c) inscribes in black letter demands less than reasonable care from manufacturers of drugs and medical devices. Its declaration that manufacturers of medical products need not make a safer product if the existing product does more good than harm reverses thirty-five years of safety-advancing products-liability law. If adopted by the courts, the rule will create a dangerous chasm in the tort law and ultimately will undermine the credibility of the ALI.

Citing the experience of hemophiliacs,⁸ who became infected with hepatitis and HIV through the use of contaminated blood products, this Essay argues that drugs, vaccines, biological products, and medical devices can and should be tested for defect by the same measures as all other products. The unsafe-design problems that section 6(c) seeks to solve can be addressed effectively by the mature and reliable functional rules of section 2—the rules applicable to all other products. Applying the alternative-safer-design standard to prescription drugs, vaccines, blood products, and medical devices would accomplish a major objective of the

§ 321(g)(1). See *United States v. Ten Cartons, More or Less*, 72 F.3d 285, 287 (2d Cir. 1995) (per curiam) (nasally administered vitamin B-12 preparation); *United States v. Dianovin Pharm.* 475 F.2d 100, 102 (1st Cir. 1973) (injectable vitamin K).

6. The term "device" is defined to include any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h). Some devices may be sold only upon prescription. See 21 C.F.R. § 801.109.

7. See *RESTATEMENT (THIRD)*, *supra* note 1, § 6(c).

8. Hemophilia A, classic hemophilia, is an X-linked hereditary blood-clotting disorder caused by defective or deficient factor VIII protein molecules. It appears worldwide in one in 10,000 male births. Hemophilia B is caused by a factor IX deficiency. See Harold R. Roberts & Maureane Hoffman, *Hemophilia and Related Conditions—Inherited Deficiencies of Prothrombin (Factor II), Factor V, and Factors VII to XII*, in *WILLIAMS HEMATOLOGY* 1413, 1413 (Ernest Beutler et al. eds., 5th ed. 1995).

ALI's *Restatement* process: culling a coherent rule from the cacophony of common-law decisions.

Part I of this Essay describes the origins of the *Restatement (Second)*'s section 402A as a draft rule protecting consumers from dangerous food products, cosmetics, and other "intimate" products, and its adoption as an expanded rule of strict liability for all kinds of defective products. It reviews the case law that emerged from the *Restatement (Second)*'s proclamation in comment *k* that selling an unavoidably dangerous but useful product would not give rise to liability for injuries caused by the product. This Part next explores the mass adoption of "blood shield laws" immunizing manufacturers of blood products from liability for defects. The Essay argues that the freedom from liability brought by the blood shield laws retarded the research, development, and implementation of pasteurizing techniques for blood derivatives. Part I also details the crippling effect of the blood shield statutes on product-defect litigation brought by hemophiliac plaintiffs infected with HIV and hepatitis from blood products.

Part II describes and criticizes the ALI's adoption in the *Restatement (Third)* of the "net benefit" test for drug and medical device liability. It argues that the new *Restatement*'s exclusion of drugs, medical devices, vaccines, and blood products from the functional standard of the alternative-safer-design test creates an undesirable fissure in the law. This Part advocates, as an alternative, a negligence-based approach that holds all manufacturers to a single standard of expertise.

Part III describes the experience of hemophiliacs in the United States in the late 1970s and early 1980s in order to illustrate the dangers of exempting medical-products manufacturers from ordinary rules of products liability. Half of the nation's hemophiliacs were infected with the AIDS virus or hepatitis before pharmaceutical companies began to market pasteurized, virus-free concentrated blood products. Without the prod of potential liability for failure to develop a safer product—a threat that was removed by the blood shield laws in forty-seven states—manufacturers did not innovate and bring safe products to market in a timely fashion. This Part criticizes the ALI's exclusion of blood products from the *Restatement (Third)*'s alternative-safer-design rule for failing to heed the lessons presented by the hemophiliacs' catastrophic experience.

Part IV discusses the shortcomings of the *Restatement (Third)*'s rationales for its special liability regime for medical products and suggests that the *Restatement* be revised to apply a consistent, fault-based liability rule for medical products and other products alike. This Part urges two standards of design-defect liability: the alternative-safer-design test for products capable of safer design, and a gross cost-benefit analysis for products not reasonably amenable to safer design. This return to the

traditional law of negligence constitutes a more coherent approach to design-defect review and gives manufacturers of medical products the incentives necessary to prevent a medical disaster like the hemophiliacs' experience from recurring.

I. THE BROAD UMBRELLA OF SECTION 402A

A. *The Old Regime: Comment k and Strict Liability to the Consumer*

The history of the *Restatement* demonstrates the power of the black-letter rule of law and the tendency of the *Restatement's* explanatory comments to become authoritative texts that set the terms of debate for many years. The *Restatement (Second)* announced in section 402A a rule that came to be called "strict liability to the consumer for defective products." Section 402A imposed liability even where the manufacturer "exercised all possible care" to avoid harm due to products in a "defective condition unreasonably dangerous to the user or consumer."⁹ For thirty years, section 402A and its comment *k* framed the debate about how liability claims relating to prescription drugs and medical devices should be adjudicated.

Section 402A ratified a body of product-defect case law emerging from the state courts in the 1960s. The New Jersey Supreme Court in *Henningsen v. Bloomfield Motors*¹⁰ and the California Supreme Court in *Greenman v. Yuba Power Products*¹¹ inaugurated a new era in the law of products liability. In the tradition of judicial innovation represented by such jurists as Benjamin Cardozo¹² and Louis

9. The section reads as follows:

Special Liability of Seller of Product for Physical Harm to User or Consumer

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND), *supra* note 4, § 402A.

10. 161 A.2d 69, 77 (N.J. 1960) (recognizing the general principle that a manufacturer's duty runs directly to the consumer when the manufacturer markets its products directly to the consumer).

11. 377 P.2d 897, 900 (Cal. 1963) ("A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.").

12. Cardozo's opinion in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916), inaugurated the modern era of consumer-protective products-liability law by imposing on an

Brandeis,¹³ the New Jersey and California Supreme Courts sought to use tort law as a tool for consumer protection. The ALI's adoption of section 402A imparted credibility to this effort because of the prestige of the ALI and the strong consensus among its leading voices that strict liability was the proper rule. With the issuance of the *Restatement (Second)*, the concept of strict liability for defective products became institutionalized.¹⁴

The first draft of section 402A called for strict liability but was limited to "food for human consumption."¹⁵ A later draft embraced all "products intended for intimate bodily use."¹⁶ The final draft adopted in 1965 extended the rule to all products.¹⁷ Section 402A contained an internal tension: Its declaration that a manufacturer would be liable even if it "exercised all possible care in the preparation and sale of [its] product" was bounded by its application only to products that were "in a *defective* condition *unreasonably* dangerous to the user or consumer or to his property."¹⁸ Thus, the section's strict-liability rule was tempered by a negligence-based concept of defect.¹⁹ Limiting section 402A's strict-liability rule further was comment *k*.²⁰ Entitled "Unavoidably unsafe

automobile manufacturer a duty of inspection to discover product defects. Cardozo, an ALI founder who played a leading role in the ALI even after he joined the United States Supreme Court, was a strong supporter of the *Restatements* as a tool to improve the law. See ANDREW J. KAUFMAN, CARDOZO 174 (1998).

13. One of Brandeis's innovations was the idea that privacy is a legally protectable right. See Louis D. Brandeis & Samuel D. Warren, *The Right of Privacy*, 4 HARV. L. REV. 193 (1890); see also *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) (asserting that individuals have the "right to be let alone").

14. The courts have hallowed the ALI's edict. James Henderson, Jr. and Aaron Twerski have noted:

Only rarely do provisions of the American Law Institute's Restatements of the Law rise to the dignity of holy writ. Even more rarely do individual comments to Restatement sections come to symbolize important, decisive developments that dominate judicial thinking. Nevertheless, section 402A of the *Restatement (Second) of Torts* is such a provision.

James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1512 (1992).

15. *Putman v. Erie City Mfg. Co.*, 338 F.2d 911, 918 (5th Cir. 1964) (quoting RESTATEMENT (SECOND) OF TORTS § 402A (Tentative Draft No. 6, 1961)).

16. *Id.* at 923 (quoting RESTATEMENT (SECOND) OF TORTS § 402A (Tentative Draft No. 7, 1962)).

17. See RESTATEMENT (SECOND), *supra* note 4, § 402A.

18. *Id.* (emphasis added).

19. Dean Prosser, who served as a Reporter for the *Restatement (Second)*, noted the tension between strict liability and negligence in section 402A: "Since proper design is a matter of reasonable fitness, the strict liability adds little or nothing to negligence [on the part of the manufacturer]; but it becomes more important in the case of a dealer who does not design the product." WILLIAM L. PROSSER, *THE LAW OF TORTS* 659 n.72 (4th ed. 1971).

20. In its entirety, comment *k* reads:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself

products,” comment *k* exempted manufacturers from liability for products in which dangers necessarily inhered. Comment *k* quickly became the usual starting point for judicial and scholarly analyses of liability for drugs, cosmetics, food, cigarettes, and alcoholic beverages.²¹ Prescription drugs, for example, were considered “unavoidably unsafe” because they could harm some users while helping others. This characteristic, combined with the safeguards erected by the FDA approval process,²² the great social utility of prescription drugs, the fact that drug use is supervised by physicians, and the fear that the uncertainties of products-liability litigation might have a chilling effect on drug innovation,²³ supported the view that drugs should not be subject to the ordinary rules of products liability.

Because a safer alternative drug design typically was unavailable, drug-defect litigation focused instead on the adequacy of instructions and warnings to reduce the incidence and seriousness of harm. Comment *k* came to be used as a defense in these cases.²⁴ Drug-design-defect litigation was relatively rare. The infrequency with which plaintiffs brought such defect claims reinforced the conventional wisdom that drugs were a special product, not to be subjected to the usual rule of strict liability.

invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND), *supra* note 4, § 402A cmt. k.

21. See W. Page Keeton, *Products Liability—Inadequacy of Information*, 48 TEX. L. REV. 398, 408-10 (1970).

22. See generally Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1788-89, 1797-99 (1996) (discussing the protracted nature of the FDA approval process).

23. See, e.g., Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 4-12 (1993) (discussing the high success rate of plaintiffs in Bendectin cases despite the paucity of evidence linking the drug to birth defects).

24. See, e.g., *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985) (“Because comment *k* itself refers to prescription drugs and vaccines as examples of products that are ‘unavoidably unsafe’ and hence not ‘unreasonably dangerous’ as long as they are properly manufactured and a proper warning is given, defendant suggests we need inquire no further before we brand the design defect evidence and instruction here as error. We prefer, however, to proceed with more caution before we confer such special protection on a product.”); see also Marc Z. Edell, *Risk Utility Analysis of Unavoidably Unsafe Products*, 17 SETON HALL L. REV. 623, 644-46 (1987) (discussing the adequacy of warnings as insulation against strict liability).

Blood products, too, were branded as “unavoidably unsafe.” This determination was codified by forty-seven states in “blood shield laws” that protected sellers of blood and blood products from strict-liability and warranty claims. Negligence claims for blood products usually were permitted, but were practically impossible for plaintiffs to win.²⁵ With the passage of time, it has been recognized that the “unavoidably unsafe” designation for blood was inaccurate—in fact, there was a practical and feasible alternative safer design for some blood products. As is described more fully in Part III, the proprietary manufacturers of anti-hemophilic factor concentrate ultimately developed pasteurization techniques that eliminated the risk of contracting HIV or hepatitis from concentrated blood products. Today, anti-hemophilic factor concentrate can be made from recombinant DNA, which, because it is artificial, transmits no blood-borne viruses or other sources of infection.²⁶

To summarize, the *Restatement (Second)*’s section 402A embodied a strict-liability rule, tempered with negligence elements, that ostensibly applied to all products. However, prescription drugs fell within the ambit of comment *k*, which rejected liability for “unavoidably unsafe” but useful products. Blood products were afforded virtual immunity from suit due to the widespread enactment of blood shield statutes by the states. The following Section discusses the way in which these rules from the era of the *Restatement (Second)* played out in the courts.

B. *Two Lines of Cases Emerge in the Era of Comment k*

Two lines of drug-design-defect cases emerged in the wake of the *Restatement (Second)*.²⁷ The main line treated drugs like other products, calling for examination of defect claims on a case-by-case basis. That line, despite wider acceptance by the courts, was rejected by the ALI in the *Restatement (Third)*. The second line, praised by the *Restatement (Third)* Reporters and cited in support of that *Restatement*’s new liability rule, opposed the imposition of strict liability for drugs (and, occasionally, for medical devices). This line of cases viewed comment *k* as a valid defense for drug manufacturers. Prescription drugs were considered “unavoidably unsafe” and were not subjected to alternative-safer-design analysis. Drugs were held to be socially desirable—and thus deserving of protection from design-defect suits—despite their dangers.

25. See INSTITUTE OF MED., HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 223 (1995) [hereinafter IOM REPORT].

26. See Jay E. Menitove et al., *Preparation and Clinical Use of Plasma and Plasma Fractions*, in WILLIAMS HEMATOLOGY, *supra* note 8, at 1649, 1650.

27. See Joanne Rhoton Galbreath, Annotation, *Products Liability: What Is an “Unavoidably Unsafe” Product?*, 70 A.L.R.4th 16 (1989) (collecting cases).

1. *The Feldman-Kearl-Toner Line*

In the *Feldman*²⁸-*Kearl*²⁹-*Toner*³⁰ line of cases, if there was a feasible alternative design choice, the product was subjected to the jurisdiction's usual doctrinal analysis for product-defect claims. In the first of the three cases, the New Jersey Supreme Court explained that it saw no reason to hold as a matter of law that all prescription drugs that are unsafe are unavoidably so:

Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability manufacturing and design defect claims under comment *k*.³¹

A year later in *Kearl*, a polio vaccine case, a California intermediate court followed *Feldman* and criticized the routine and mechanical fashion in which many appellate courts had concluded that certain products, particularly drugs, were entitled to such special treatment. The court observed that the "statement that drugs are unavoidably [dangerous], and therefore within the protection of comment *k*, has become almost tautological."³² The court emphasized that "whether a drug, vaccine, or any other product . . . triggers unavoidably dangerous product exemption from strict liability design-defect analysis poses a mixed question of law and fact and can be made only after evidence is first taken, out of the jury's presence, on the relevant factors to be considered."³³

In *Toner*, a DPT (diphtheria, pertussis, and tetanus) vaccine case, the Idaho Supreme Court embraced *Kearl* and *Feldman*, explaining:

As an additional element of an "unavoidable risk," there must be, at the time of the subject product's distribution, no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk. If there were, then the risk would not be "unavoidable" or "apparently reasonable." Nor would the "marketing and use of the [product] be fully justified" if there were such an alternative design

. . . .

28. *Feldman v. Lederle Lab.*, 479 A.2d 374, 383 (N.J. 1984).

29. 218 Cal. Rptr. at 463-64.

30. *Toner v. Lederle Lab.*, 732 P.2d 297, 306-08 (Idaho 1987) .

31. *Feldman*, 479 A.2d at 383.

32. *Kearl*, 218 Cal. Rptr. at 463 (citation omitted).

33. *Id.* at 463-64 (citation omitted).

... We do not believe comment *k* was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability design defect claims.³⁴

The *Feldman-Kearl-Toner* approach has resolved single-drug,³⁵ combination-drug,³⁶ vaccine,³⁷ and medical-device³⁸ cases in two ways. If a redesign was considered available—in other words, if the drug ingredients could be changed or the device mechanically redesigned without affecting efficacy—then the court treated the medical product like any other product. It allowed the case to proceed to trial under the jurisdiction's prevailing approach to products-liability risk-utility analysis. If, however, no redesign appeared feasible, and the product was therefore “unavoidably unsafe,” the seller was relieved of liability so long as the warnings accompanying the product were adequate and the product was judged to do more good than harm. This analysis involved weighing the product's overall utility against its dangers for foreseeable users. Dangerous but socially desirable products were held to be exempt from strict liability. The classic illustration was comment *k*'s reference to the highly injurious Pasteur rabies vaccine,³⁹ which presented the potentially infected person with a choice between the dangers of the vaccine and the risk of a dreadful illness and swift death.

34. *Toner*, 732 P.2d at 306-08 (citations omitted).

35. See *Davila v. Bodelson*, 704 P.2d 1119, 1127-28 (N.M. Ct. App. 1985) (holding that for the drug Pitocin, since no alternative safer design was available, the only relevant issue was the drug's utility to users); *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 781 (R.I. 1988) (holding that for DES, courts should follow a case-by-case approach in deciding whether to extend comment *k* protection).

36. Oral contraceptives are one example of a combination drug. See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) (applying the alternative-safer-design test to an oral contraceptive); *West v. Searle & Co.*, 806 S.W.2d 608 (Ark. 1991) (same); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410 (Colo. 1986) (en banc) (finding sufficient evidence to conclude that the oral contraceptive at issue was beneficial for at least one class of users and holding that the alternative-safer-design question should be submitted to the jury).

37. See *Rohrbough v. Wyeth Lab.*, 719 F. Supp. 470, 476-77 (N.D. W. Va. 1989), *aff'd*, 916 F.2d 970 (4th Cir. 1990) (holding that in order to raise a comment *k* defense, the manufacturer must show that its DTP vaccine was “unavoidably unsafe”); *White v. Wyeth Lab.*, 533 N.E.2d 748, 752 (Ohio 1988) (observing, in a case concerning the DTP vaccine, that comment *k* “[o]bviously . . . does not apply to all drugs” and noting that “[i]t is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks”).

38. The medical devices reviewed in these cases include intrauterine devices, implants, and surgical contrast fluids. See *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337-39 (9th Cir. 1985) (upholding a jury's conclusion that the Dalkon Shield intrauterine device was defective under the alternative-safer-design test); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988) (Cu-7 intrauterine device); *Savina v. Sterling Drug*, 795 P.2d 915, 925-27 (Kan. 1990) (concluding that the myelogram dye metrizamide is unavoidably unsafe); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 887 (Okla. 1994) (penile implant).

39. See RESTATEMENT (SECOND), *supra* note 4, § 402A cmt. k (noting that the rabies vaccine “not uncommonly leads to very serious and damaging consequences when it is injected,” but nonetheless was not unreasonably dangerous given the grave consequences of the disease it prevented).

2. *The Brown Line: Exemption from Strict Liability*

A second line of cases emerged in the comment *k* era following *Brown v. Superior Court*.⁴⁰ In these cases, the courts held that the product categories of prescription drugs and medical devices were “unavoidably unsafe,” or were so useful that the manufacturers of these products should not be subject to strict liability even if the drug or device could have been designed more safely. In *Brown*, the California Supreme Court adjudicated the consolidated claims of sixty-nine children who suffered in utero damage due to their mothers’ ingestion of the carcinogenic anti-miscarriage drug DES. The court rejected the *Kearl* approach of treating the question of whether a drug’s dangers are “unavoidable” as a question of fact and found in favor of the manufacturer.⁴¹

The *Brown* court, eschewing strict liability, rejected for design defects in drugs⁴² even the negligence-based, risk-utility framework it had adopted ten years earlier in *Barker v. Lull Engineering*.⁴³ *Brown* did leave the door open for some form of negligence liability, but resoundingly rejected strict liability on policy grounds:

If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.⁴⁴

In the three decades following section 402A’s publication, comment *k* was widely recognized as setting a negligence, rather than a strict-liability, standard. Because drugs were so often deemed unavoidably unsafe, liability analyses usually focused either on warnings or on the product’s overall utility, rather than any specific aspect of product design. As risk-utility tests such as those espoused by Wade⁴⁵ and

40. 751 P.2d 470 (Cal. 1988).

41. *See id.* at 481-83.

42. A California appellate court extended the reasoning of *Brown* to silicone breast implants, which are considered a medical device. *See Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1397 (Ct. App. 1994) (“We . . . conclude that the entire category of medical implants available only by resort to the services of a physician are immune from design defect strict liability.”).

43. 573 P.2d 443, 452-57 (Cal. 1978) (establishing dual approaches to defining product defects: the consumer-expectations test and negligence-based risk-utility analysis).

44. *Brown*, 751 P.2d at 479.

45. *See Wade, supra* note 2, at 837-38.

Keeton⁴⁶ came to dominate design-defect analysis, strict liability to the consumer increasingly was confined by the courts to manufacturing defects and to merchants' vicarious liability. The strict-liability label persisted, however,⁴⁷ creating confusion in judicial opinions. The California Supreme Court's opinion in *Brown*, for example, labeled risk-utility analysis a form of strict liability, rather than a negligence-based standard.⁴⁸

3. *The Blood Test: Exclusion from Products-Liability Law by Legislation*

The law surrounding blood and blood products developed somewhat differently from that governing defect claims for prescription drugs, vaccines, and medical devices. Not long after the promulgation of section 402A, an epidemic of transfusion-associated hepatitis dramatically affected the course of product-defect law for blood products. The idea of strict products liability began to seize the imaginations of judges, lawyers, and academic commentators as a possible means of combating the epidemic, or at least of compensating its victims. Professor Marc Franklin, for example, expressed some skepticism that strict liability could succeed in providing compensation or deterring defective designs, but nonetheless argued that the "safety incentive justification" was a "compelling basis for strict liability."⁴⁹ He reasoned that the blood banks and hospitals were "in the best position to analyze safety techniques and their costs"; therefore, tort law should place the burden on them to manufacture and use blood products safely.⁵⁰ Franklin noted, however, that the law was "caught between conventional strict-liability analysis for defective products, reflected in recent court opinions, and the opposing claim that liability in the healing professions should be based on fault alone, which is the position taken by many legislatures."⁵¹

46. See Page Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 37-38 (1973) (stating that the determination that a product is unreasonably dangerous turns on the question of whether, on balance, the danger presented by the product outweighs its utility, so that a reasonable man would not sell the product if he knew the risk involved).

47. See *Feldman v. Lederle Lab.*, 479 A.2d 374, 385 (N.J. 1984) (determining that "[t]he question in strict liability design-defect and warning cases is whether, assuming that the manufacturer knew of the defect in the product, he acted in a reasonably prudent manner in marketing the product or in providing the warnings given" and observing that "[t]hus, once the defendant's knowledge of the defect is imputed, strict liability analysis becomes almost identical to negligence analysis in its focus on the reasonableness of the defendant's conduct."); see also David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, 1996 U. ILL. L. REV. 743 (arguing that "strict liability" is often a negligence standard in practice).

48. See *Brown*, 751 P.2d at 474.

49. Marc A. Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439, 479 (1972).

50. *Id.*

51. *Id.*

But strict liability never was applied to blood products. Negligence-based claims remained available as a hypothetical remedy for and possible deterrent to the manufacture and use of unsafe blood products. Due to lobbying by hospitals, physicians, and blood banks, however, state legislatures spurned the strict products-liability remedy. Instead, they enacted blood shield statutes en masse in response to section 402A. In 1965, three states had blood shield laws; by 1972, the count was forty-one.⁵² These statutes made it clear that the "healing professions," including hospitals and both nonprofit and proprietary⁵³ manufacturers of blood products, were to be judged more deferentially than other producers and sellers. They would be untouched by modern products-liability law, even though William Prosser, ALI Reporter and godfather of the strict-liability movement, had viewed blood products as proper subjects of fault-based design-defect review:

There are a number of cases involving hepatitis resulting from blood transfusions . . . [which have] been regarded by most courts as a service, and not a sale. . . . But a blood bank which supplies the blood is certainly to be regarded as a seller; and the general refusal to hold it strictly liable has gone on the basis of the unavailability of the danger. [*However, when*] any evidence can be produced that it might have been avoided, it becomes a question for the jury, and may lead to liability.⁵⁴

The rationale for the legislative departure from this viewpoint was that the work of blood banks and health care providers was of such great social importance that it should be allowed to proceed unhampered by the threat of litigation. Arkansas's 1971 blood shield statute exemplifies this understanding, finding as legislative fact that the "imposition of legal liability without fault upon the persons and organizations engaged in such scientific procedures inhibits the exercise of sound medical judgment and restricts the availability of important scientific knowledge, skills, and

52. See *id.* at 474-75. Ultimately, 47 states passed blood shield laws. See IOM REPORT, *supra* note 25, at 48. The jurisdictions that left the issue to the common law were New Jersey, the District of Columbia, Rhode Island, and Vermont. See *id.*

53. The dominant nonprofit force in the blood industry was the American Red Cross, which in the first half of the 1970s accounted for about half of the blood used in America, over five million units a year. See DOUGLAS STARR, BLOOD: AN EPIC HISTORY OF MEDICINE AND COMMERCE 252 (1998). Community blood banks, united in the rival American Association of Blood Banks, collected over 35% of the nation's blood supply. See *id.* Proprietary companies expanded during the 1970s and by the end of the decade had bought out almost a third of the nearly 400 blood collection centers in the United States. See *id.* at 258. Four major companies controlled most of the world's plasma, which was "becoming an integrated resource, mixed and distributed all over the world." *Id.* at 258-59.

54. PROSSER, *supra* note 19, at 661-62 (emphasis added).

materials.”⁵⁵ Therefore, declared the legislature, it was “the public policy of this state to promote the health and welfare of the people by limiting the legal liability arising out of such scientific procedures to instances of negligence or willful misconduct.”⁵⁶

Two tiers of products-liability law thus emerged in the era of comment *k*, with legislative sanction. There was a general trend in the common law to ground defect claims in what Prosser had recognized as the negligence heart of products-liability law. But blood products, even those produced by for-profit commercial entities, were excluded from this regime. Most state legislatures codified the unique treatment of blood, but even in the common-law states, “the likelihood that a court would hold a hospital or blood donor service liable under either breach of implied warranty or strict-liability theories was considered remote.”⁵⁷

These legislative determinations held fast, even as the impact on the public health of immunizing the blood banks from liability became clear. The hepatitis A and B epidemics persisted in the 1970s, and “non-A, non-B” hepatitis emerged. The incidence of hepatitis among hemophiliacs grew as proprietary pharmaceutical companies increased their production capacity. The companies established commercial blood collection centers in Africa, Latin America, and many American prisons in order to meet the demand for pooled anti-hemophilic factor (AHF) plasma products, which they sold both domestically and globally. This collection of blood from prisoners and others at high risk for hepatitis greatly increased the incidence of the disease in the blood supply, and thus the dangers to hemophiliacs, who depended on the unpasteurized, pooled blood products.⁵⁸

Despite the growing risks, no lobbyists for the jaundiced walked the legislative halls. Potential plaintiffs’ lawyers saw no prospect of success in the face of blood shield laws that foreclosed strict-liability and implied warranty causes of action, which were the principal doctrinal tools of products-liability litigation. Shielded from suit, the blood industry had no incentive to pursue research and development of pasteurization techniques to reduce the risk of contracting hepatitis (and later HIV) from the blood supply. The blood shield laws thus allowed the blood industry to continue to make blood products that were *avoidably* unsafe, at tremendous cost to human life. Not until well after the third wave of viral infection—HIV—devastated hemophiliacs in the early 1980s did design-defect suits begin to

55. ARK. CODE ANN. § 20-9-801(b) (Michie 1987).

56. *Id.* § 801(c). The legislature extended this protection to all individuals and entities providing any “tissue, organ, blood, or component thereof.” *Id.* § 802. California followed a somewhat different approach, excluding blood from the law of warranty. It removed the subject from the law of sales and placed it within the ambit of professional negligence, which is governed by the customary standard of care. See CAL. HEALTH & SAFETY CODE § 1606 (West 1990).

57. IOM REPORT, *supra* note 25, at 48.

58. See STARR, *supra* note 53, at 231-49.

emerge. Hobbled by the blood shield laws, this litigation did little to compensate the hemophiliac victims of the epidemics. Although in the 1990s two state legislatures passed laws affording a tort remedy to hemophiliacs infected with HIV,⁵⁹ this legislative response was too little, too late.

II. THE *RESTATEMENT (THIRD)* SECTION 6(C): THE PROPOSED NEW REGIME

A. *The Net Benefit Test*

Design-defect litigation centers on the search for a safer mousetrap—safer for the trapper, that is. Under the general rule of *Restatement (Third)* section 2, designs that unreasonably fail to use available techniques to increase safety are held to be defective.⁶⁰ If there is no practical safer-design choice, the seller has two options: decline to market the product or render it reasonably safe by means of warnings and instructions for use. In design-defect litigation, this standard is implemented by asking the factfinder to decide whether the manufacturer's failure to adopt a design feature proposed by the plaintiff was, on balance, right or wrong.⁶¹ In section 6(c)

59. See N.J. STAT. ANN. § 2A:14-26.1 (West Supp. 1999); N.Y. C.P.L.R. § 214-c (Consol. Supp. 1999). The New Jersey legislature explained that it was acting to assure that HIV-infected hemophiliacs would get "their day in court." A New Jersey court, upholding the statute, found that holding proprietary blood products manufacturers accountable was "consistent with one of the overriding purposes of product liability law—to spread the burden of damages which flow from such injuries onto those responsible for the products' design and manufacture." *D.J.L. v. Armour Pharm. Co.*, 704 A.2d 104, 117 (N.J. Super. Ct. Law Div. 1997) (footnote omitted).

60. See *RESTATEMENT (THIRD)*, *supra* note 1, § 2. The general rule is that

[a] product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

....

- (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
- (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Id.

61. David G. Owen has observed that while courts generally define the balance in terms of a weighing of the product's *global* costs and benefits, what juries actually decide is typically "the much more narrow 'micro-balance' of the costs and benefits of the particular design feature that the plaintiff claims the manufacturer ought to have adopted." David G. Owen, *Risk-Utility Balancing in Design Defect Cases*, 30 U. MICH. J.L. REFORM 239, 239 (1997) [hereinafter Owen, *Risk-Utility Balancing*]; see also David G. Owen, *Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits*, 75 TEX. L. REV. 1661, 1687 (1997). The *Restatement (Third)* embraced the "micro-balancing" approach. See *RESTATEMENT (THIRD)*, *supra* note 1, § 2 cmt. f Reporter's note.

of the *Restatement (Third)*, the ALI prescribed a different liability standard for prescription drugs, vaccines, and medical devices. Known as the “net benefit test,” this standard states:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.⁶²

Thus, if the medical product does more harm than good for at least one class of users, it will not be considered defective. This is true even if the product *unnecessarily* causes harm, in the sense that there is a feasible safer alternative design. Section 6(c) mirrors the “manifestly unreasonable” design standard recognized (somewhat grudgingly) in section 2, which states that some product designs have such low social utility and are so dangerous that liability should attach even absent proof of a reasonable alternative design.⁶³ Section 6(c) is also notable in that it represents a “product category” approach to liability rules even though the ALI elsewhere rejected the categorical approach.⁶⁴

The net benefit rule is a standard under which liability rarely will be imposed. Indeed, a design-defect claim will not survive even the summary judgment stage unless the court determines that a reasonable person could conclude that the product was defective under this narrow standard.⁶⁵ While it is true that for most prescription drugs there is no alternative safer design, this is not *always* the case. Moreover, that fact does not logically compel a categorical doctrinal exception for all such drugs, vaccines, and medical devices—a group of products that has in common only the fact that they are prescribed or administered by a licensed health care provider. By any

62. *Id.* § 6(c). For an example of a judicial interpretation of the net benefit test, see *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), a suit by a child who contracted polio from the Sabin oral live polio vaccine in which the court held that an unavoidably unsafe product is *unreasonably* dangerous only if it is “so dangerous that a reasonable man would not sell the product if he knew the risk involved.” *Id.* at 1273-74.

63. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. e. The section 6(c) standard also bears some resemblance to a negligence-based marketing liability standard proposed by Joseph Page for generic product-defect cases. See Joseph A. Page, *Liability for Unreasonably and Unavoidably Unsafe Products: Does Negligence Doctrine Have a Role To Play?*, 72 CHI.-KENT. L. REV. 87, 127-28 (1996) (arguing that a product’s dangers may be so great as to make its sale unreasonable even in the absence of a feasible safer alternative design).

64. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. d (clarifying that the reasonable alternative-safer-design standard “applies in most instances even though the plaintiff alleges that the category of product sold by the defendant is so dangerous that it should not have been marketed at all”).

65. See *id.* § 6 cmt. f.

measure, section 6(c) is an aberration, and an unjustifiable one. How, then, did it come into being?

B. *The Proceedings of the ALI: Deliberation and Omission*

The American Law Institute debated the new products-liability *Restatement* at five annual sessions from May 1994 through April 1998. Vigorous debate characterized the consideration of the main liability proposals in section 2, particularly the abandonment of the traditional consumer-expectations test for product defect and the adoption of the reasonable alternative design standard.⁶⁶ The debate over these provisions carried over from the floor to the academic literature.⁶⁷ ALI Reporters James Henderson and Aaron Twerski widely disseminated and defended their views as the project advanced.⁶⁸ As a result, they were successful in preserving the main lines of their initial proposals through successive drafts of the new *Restatement*.

The Reporters had been harsh critics of the strict-liability movement⁶⁹ and section 402A's comment *k*. The comment's 275 words on drug products liability had been exhaustively parsed, praised, and appropriated by opposing combatants for thirty years, and the Reporters were eager for a fresh start on the question of drug products liability. They renounced even the possibility of simply restating the law of drug products liability: "Case law that is unintelligible cannot be intelligibly restated. There is a need in

66. See 74 A.L.I. PROC. 892-902 (1997); 73 A.L.I. PROC. 136-64 (1996); 72 A.L.I. PROC. 104-40 (1995); 71 A.L.I. PROC. 272-87 (1994).

67. See William A. Dreier, *Design Defects Under the Proposed Section 2(b) of the Restatement (Third) of Torts: Products Liability: A Judge's View*, 30 U. MICH. J.L. REFORM 221 (1997); Oscar S. Gray, *The Draft ALI Product Liability Proposals: Progress or Anachronism?*, 61 TENN. L. REV. 1105 (1994); Michael D. Green, *The Schizophrenia of Risk-Benefit Analysis in Design Defect Litigation*, 48 VAND. L. REV. 609, 622-23 (1995); Mark McLaughlin Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus on Warning Law Is Wrong*, 61 TENN. L. REV. 1125 (1994); Owen, *supra* note 47, at 743; David G. Owen, *The Graying of Products Liability Law*, 61 TENN. L. REV. 1241 (1994); Page, *supra* note 63, at 87; Jerry J. Phillips, *Achilles' Heel*, 61 TENN. L. REV. 1265 (1994); Marshall S. Shapo, *A New Legislation: Remarks on the Draft Restatement of Products Liability*, 30 U. MICH. J.L. REFORM 215 (1997); John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Products Liability Design Defects*, 26 U. MEM. L. REV. 493 (1996); Ellen Wertheimer, *The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement*, 61 TENN. L. REV. 1429 (1994).

68. See James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867 (1998); James A. Henderson, Jr. & Aaron D. Twerski, *Arriving at Reasonable Alternative Design: The Reporters' Travelogue*, 30 U. MICH. J.L. REFORM 563 (1997); James A. Henderson, Jr. & Aaron D. Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667 (1998); James A. Henderson, Jr. & Aaron D. Twerski, *Will a New Restatement Help Settle Troubled Waters: Reflections*, 42 AM. U. L. REV. 1257 (1993); Aaron Twerski, *From a Reporter's Perspective: A Proposed Agenda*, 10 TOURO L. REV. 5 (1993).

69. See Henderson & Twerski, *supra* note 2, at 1286-92.

this area to clarify the issues and to provide direction to the courts as to how this very special genre of cases can be sensibly approached.”⁷⁰

Although their original proposals concerning what ultimately became section 6(c) spoke only of prescription drugs,⁷¹ the Reporters’ Tentative Draft Number 1 extended this highly manufacturer-protective standard to prescription medical devices.⁷² Surprisingly, this change sparked no debate on the floor of the Institute’s annual meetings. Through several drafts, no amendment was offered and no one challenged the exemption of both prescription drugs and medical devices from the alternative-safer-design standard embodied in section 2.⁷³ The ALI also quietly acquiesced in the exclusion of blood products from the liability rule of section 2, declaring in section 19(c) of the *Restatement (Third)* that “[h]uman blood and human tissue, even when provided commercially, are not subject to the rules of this *Restatement*.”⁷⁴

Academic commentators criticized the ALI’s proposed rule for drugs as setting a “super-negligence” standard of liability⁷⁵ and argued in favor of either negligence-based⁷⁶ or strict-liability-

70. Henderson & Twerski, *supra* note 14, at 1545; *see also id.* at 1537 (“The problem can in large part be attributed to the existing comment *k*, which is poorly drafted and internally inconsistent. . . . To draw on comment *k* as authority to resolve problems that no one even contemplated at the time of its adoption is sheer foolishness.”).

71. *See id.* at 1522-23 (presenting proposed revisions of comment *k*).

72. Tentative Draft Number 1 proposed that plaintiffs should be required to prove that “[t]he foreseeable risks of harm posed by the *drug or medical device* were sufficiently great in relation to its therapeutic benefits as to deter a reasonable medical provider, possessing knowledge of such foreseeable risks and therapeutic benefits, from prescribing the *drug or medical device* for any class of patients.” Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1365 n.40 (1994) (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b)(4), at 89 (Tentative Draft No. 1, 1994)) (emphasis added).

73. The only negative word spoken on the floor concerning the proposed standard was Professor Howard Latin’s comment at the 1995 meeting that section 8(c) (later section 6(c)) was “very, very friendly to drug manufacturers.” 72 A.L.I. PROC. 281 (1995). There was some floor debate concerning Latin’s suggestion that section 6(c)’s language be changed from “no reasonable health care provider” to “reasonable health care providers.” *See id.* at 276. This amendment was accepted by the Reporters as a way of emphasizing the objective rather than the subjective nature of the standard. There was also debate over another motion by Latin concerning potential liability in situations in which the manufacturer knows that its drug or device is “being prescribed to a class of patients for whom the ratio of foreseeable risks to therapeutic benefits exceeds the risk-to-benefit ratio afforded by a reasonable alternative design or reasonable alternative product.” *Id.* at 869-70. This motion was defeated.

74. RESTATEMENT (THIRD), *supra* note 1, § 19(c).

75. *See, e.g.,* Schwartz, *supra* note 72, at 1364 (“[T]he proposal [would] establish[] a ‘super’ negligence standard of liability. . . . [T]he proposed standard . . . will create such a narrow band of liability that it would effectively eliminate a cause of action for defective design.”).

76. *See* Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 110 (1994) (advocating a “pure negligence” standard as “an appropriate middle step” between strict liability and the *Restatement*’s near-immunity); Angela C. Rushton, Comment, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 420, 435 (1996) (criticizing the *Restatement*

based⁷⁷ standards of drug-design-defect review. Henderson rejected these criticisms, urging "substantial deference to a marketplace for prescription drugs that appears to function almost perfectly."⁷⁸ Additional academic criticism was leveled by Michael Green, an ALI Adviser, who supported section 6(c) for drugs but questioned its suitability for medical devices and vaccines, which he believed were more readily subject to design improvements.⁷⁹

But the Reporters never had to respond to these criticisms on the Institute floor. The silence from the floor is mystifying. The Reporters' assertions were vulnerable to criticism not only because of the proposed new rule's manufacturer-friendliness, but also because the common-law basis for the rule was thinly documented.⁸⁰ Indeed, the Reporters had

(*Third*) approach as insufficiently protective of consumers but conceding that "a drug should receive the protection of a heightened liability standard . . . when its benefits outweigh its risks").

77. See Frank J. Vandall, *Constructing a Roof Before the Foundation Is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect*, 30 U. MICH. J.L. REFORM 261, 270-71, 279 (1997) (advocating strict liability for drug-design defects and criticizing section 6(c) for "clearly favoring manufacturers by eliminating strict liability, skirting negligence, and adopting a radical new theory with little attempt to balance the interests of the consumers").

78. James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 481 (1996).

79. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461 (1997) [hereinafter Green, *Statutory Compliance*]. Green commented:

The analysis for design defects in drugs is quite different and driven by the unique character of most drugs. Unlike durable goods, drugs cannot be designed in an alternative fashion, at least not in light of current technological capabilities. With the *Restatement (Third)*'s adoption of a risk-benefit test for design defects and its insistence on proof of an alternative design, one might think that there would therefore be no place for a design defect theory involving pharmaceuticals.

. . . .

But the *Restatement (Third)* does have a very limited provision for a design defect claim in the case of pharmaceuticals

Id. at 471 (footnotes omitted). Green clarified in a footnote that "[t]his observation is inapplicable to medical devices. Pharmaceuticals differ from most products because it is difficult to change the design of a given drug; medical devices, such as the Dalkon Shield with a multifilament tailstring, although subject to FDA regulation, do not share that characteristic with drugs." *Id.* at 471 n.36; see also Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 208 n.4 (1999) (suggesting that while section 6(c) may be an appropriate regime for prescription drugs, medical devices and vaccines may be sufficiently different from drugs as to require a different liability rule); Green, *supra* note 67, at 619-20 (suggesting that vaccines are appropriate subjects of alternative-safer-design analysis).

80. Compare the *Restatement (Third)* Reporters' notes' thorough state-by-state review of cases in support of section 2's alternative design standard with the Reporters' sparse defense of the section 6(c) rule. See RESTATEMENT (THIRD), *supra* note 1, §§ 2, 6 Reporters' notes. In their section 6(c) note, the Reporters assert that courts "traditionally have refused to review the reasonableness of the designs of prescription drugs and medical devices." *Id.* § 6 cmt. f Reporter's note. Fifteen jurisdictions are cited that do not follow the traditional "no review" rule and only six states are identified that "have adopted essentially the approach taken in § 6(c)." *Id.* Moreover, one of those six state cases, *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994), in fact notes the appropriateness of the alternative-safer-design test for review of medical devices. See *id.* at 886.

announced that they were not even attempting to restate the law. On the contrary, as the review of the case law presented in Part II of this Essay demonstrates, the courts have adjudicated drug and medical device cases using the analytical tools underlying section 2. Their decisions did not point in the direction of the rule embodied in section 6(c).⁸¹ Thus, the ALI adopted section 6(c) without benefit either of floor debate or of a solid bedrock of judicial decisions. In contrast, the alternative-safer-design test of section 2 is well grounded in the common law.

The alternative-safer-design test has great potential to rescue products-liability law from critics who see it as unpredictable or as a blunt, punitive instrument.⁸² It provides a means of resolving the two lines of design-defect cases from the era of comment *k*, the *Feldman-Kearl-Toner* line and the *Brown* line. Furthermore, the alternative-safer-design test relies on a method of analysis that courts are particularly competent to perform: comparison of the facts of the actual case with a hypothetical set of facts.⁸³ This type of analogical dialogue is the dominant form of lawyers' reasoning and is found throughout the common law. Because the ALI's section 6(c) rule abandons the comparative method of product-defect analysis, courts that adopt it will deprive themselves of one of the common law's most powerful analytical tools. The ALI's failure to apply the alternative design test of section 2 to prescription drugs and medical devices evinces a lack of appreciation of the strength of the comparative approach.

A further advantage of the alternative-safer-design test is its accessibility to lay juries. The test focuses the jury on the designer's choice regarding concrete particulars rather than on abstract questions that have befuddled judges and juries, such as whether the product's benefits outweigh its dangers or whether certain categories of products should be

81. The Reporters' departure from the dominant common-law rules was evident. In their first alternative revision of comment *k*, the Reporters stated that courts had traditionally limited drug-defect claims to failure-to-warn theories, see Henderson & Twerski, *supra* note 14, at 1512, an approach the Reporters had long disparaged, see, e.g., James A. Henderson & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure To Warn*, 65 N.Y.U. L. REV. 265 (1990). That statement may be an accurate summary of how the bulk of drug products-liability cases have been litigated in the past, but it does not accurately capture the current majority rule.

82. See, e.g., JULES L. COLEMAN, RISKS AND WRONGS, 414-15 (1992) ("Together the rule of strict liability in conjunction with the design defect tests have wreaked havoc within the manufacturing sector of the economy. . . . [T]he modern solution has failed to provide what we seek, a principled, rational, and predictable body of law regulating product safety."); RICHARD A. EPSTEIN, SIMPLE RULES FOR A COMPLEX WORLD 103 (1995) ("Breakthroughs in technology and treatment need carrots, not sticks.").

83. See Gary T. Schwartz, *Foreword: Understanding Products Liability*, 67 CAL. L. REV. 435, 468 (1979) (noting that "one simply cannot talk meaningfully about a risk-benefit defect in a product design until and unless one has identified some design alternative" to serve as a referent); see also Cass R. Sunstein, *On Analogical Reasoning*, 106 HARV. L. REV. 741, 790-91 (1993) (expounding the virtues of analogical reasoning in judicial decisionmaking).

marketed at all.⁸⁴ It enables persons of different values and experience to bridge the gaps among them and reach principled agreement.

The ALI's failure to adopt the comparative approach is regrettable. Adhering to a gross cost-benefit method of products-defect analysis that it has elsewhere found wanting,⁸⁵ the ALI in section 6(c) has replaced the doctrinal wars over strict and negligence standards of liability with a conflict derived from the adoption of different liability rules for different industries. The ALI exempted a favored industry from the comparative design-choice analysis imposed on all other producers, and if the courts follow this rule, they too will find themselves playing favorites. Courts rejecting the alternative-safer-design test for medical industries also will abandon an analytical tool that could prove increasingly useful as genetic engineering and microbiology advance and the range of design choices for pharmaceutical product designers becomes broader and less opaque.⁸⁶ The *Restatement (Third)* and its Reporters' notes ignore this prospect.⁸⁷ The consequences of maintaining a separate, highly protective liability regime for manufacturers of blood products are described in the following Part.

III. MANUFACTURED CATASTROPHE:

THE HIV AND HEPATITIS EPIDEMICS AMONG HEMOPHILIACS

A. *The Hepatitis and HIV Epidemics and the Blood Industry*

Individuals with hemophilia rely upon blood coagulation products, called "factor concentrate," to alleviate the effect of their inherited deficiency in a protein that is necessary for normal blood clotting. Factor concentrate is manufactured from blood plasma collected from thousands of different donors.⁸⁸ Consequently, hemophiliacs are exposed, in the normal course of treatment, to a high risk of infection by blood-borne viruses.

84. See Owen, *Risk-Utility Balancing*, *supra* note 61, at 239 (describing the courts' struggle to frame the defect question in terms of global product risks and benefits as "balancing bedlam").

85. See *RESTATEMENT (THIRD)*, *supra* note 1, § 2 cmt. e.

86. Many drugs commonly are understood to be unalterable in design, but this is not necessarily the case. The possibility of alternative designs is acknowledged by the FDA. The section of the Food, Drug & Cosmetic Act dealing with orphan drugs, for example, implicitly recognizes the possibility that two different manufacturers could produce two different versions of the same drug. See 21 U.S.C. § 360cc (1994); see also 21 C.F.R. § 316.3 (1999) (defining "same drug"). Orphan drugs are vaccines and other drugs intended for the treatment of rare diseases.

87. The Reporters did recognize in two law journal articles that competing designs for vaccines presented serious challenges to their position that drugs should be insulated from alternative design review, but this concern was nowhere manifested in the *Restatement (Third)*. See Henderson, *supra* note 78, at 490-91; Henderson & Twerski, *supra* note 14, at 1539-40.

88. See IOM REPORT, *supra* note 25, at 1. Recombinant factor VIII is now available, but the product had not yet been invented at the time of the hepatitis and HIV epidemics. See Menitove et al., *supra* note 26, at 1654.

A massive epidemic of hepatitis struck hemophiliacs in the 1970s, transmitted through factor concentrate and other blood products. A new strain of "non-A, non-B" hepatitis (later labeled "C") was identified in the mid-1970s and became the dominant element in the epidemic.⁸⁹ Physicians quickly realized during this period that the pandemic of hepatitis among hemophiliacs was linked to the increasing use of factor-concentrate therapy in North America, Europe, and Japan. In 1972, the National Transfusion Hepatitis Study found that fifty-one percent of hemophiliacs with significant exposure to factor VIII concentrated blood products had liver dysfunction, and all recipients of fractionated products had antibodies for the hepatitis B virus.⁹⁰ Another study five years later found an eighty-four percent infection rate among hemophiliacs and noted that the pattern of liver disease among hemophiliacs paralleled that among drug addicts.⁹¹ One factor explaining this high rate of infection was that the clotting products on which hemophiliacs relied were composed of plasma pooled from thousands of donors, and plasma from a single infective donor contaminated the entire pool.⁹²

Despite the dangers associated with factor concentrates, physicians concluded that treatment with these blood products provided a net benefit to hemophiliacs.⁹³ Even when the risk of HIV transmission through blood

89. See E. Tabor & R.J. Gerety, *Non-A, Non-B Hepatitis: New Findings and Prospects for Prevention*, 19 TRANSFUSION 669, 669 (1979) (stating that nearly 89% of cases of transfusion-associated hepatitis in the United States in 1979 were "non-A, non-B" hepatitis and that the risk of contracting that form of hepatitis from a blood transfusion in the United States was between 5.4% and 18.5%). Hepatitis A is transmissible through a variety of means and has a short incubation period. Its symptoms are flu-like and may have a protracted course, but it only rarely causes liver failure. Hepatitis B is a chronic viral disease that causes a variety of acute and chronic problems in the liver and other organ systems. About 90% to 95% of otherwise healthy adults recover completely from hepatitis B, but 5% to 10% remain chronically infected. Hepatitis C is a chronic disease in 50% to 80% of cases. Ten percent to 20% of hepatitis C patients suffer from cirrhosis or progressive liver failure. See Robert K. Ockner, *Acute Viral Hepatitis*, in CECIL TEXTBOOK OF MEDICINE 762 (J. Claude Bennett & Fred Plum eds., 1996); Robert K. Ockner, *Chronic Hepatitis*, in CECIL TEXTBOOK OF MEDICINE, *supra*, at 776.

90. See George F. Grady et al., *Risk of Posttransfusion Hepatitis in the United States: A Prospective Cooperative Study*, 220 JAMA 692, 692-701 (1972).

91. See M.W. Hilgartner & P. Giardina, *Liver Dysfunction in Patients With Hemophilia A, B, and von Willebrand's Disease*, 17 TRANSFUSION 495, 497 (1977). The high rate of infection may have been attributable in part to commercial blood banks' increased use of blood donors from prisons, indigent neighborhoods, and Third World countries, where rates of hepatitis infection were high. See STARR, *supra* note 53, at 231-49.

92. See Grady, *supra* note 90, at 700.

93. See U.W. Hasiba et al., *Chronic Liver Dysfunction in Multitransfused Hemophiliacs*, 17 TRANSFUSION 490, 493 (1977) (concluding that "single donor products should be the preferred mode of treatment for mild hemophiliacs who require only infrequent therapy"); see also E.D. Gomperts et al., *Hepatocellular Enzyme Patterns and Hepatitis B Virus Exposure in Multitransfused Young and Very Young Hemophilia Patients*, 11 AM. J. HEMATOLOGY 55, 59 (1981) (concluding that "because the long-term clinical consequences of this hepatocellular dysfunction are currently unknown, and as the danger and problems associated with hemorrhagic episodes are well-characterized, under current knowledge it would seem inadvisable to withhold

became known in the 1980s,⁹⁴ reasonable health care providers continued to prescribe factor concentrate to hemophiliacs because often there was no alternative. The imminent threat to life presented by hemophilia-related emergencies was deemed more compelling than the risk of contracting a chronic illness from the blood products used to respond to these emergencies.

There also was a culture of inevitability about illness among hemophiliacs. The Institute of Medicine reported that “[h]epatitis was viewed as an acceptable risk by the government regulatory agencies responsible for the safety of blood and blood products, the plasma fractionation industry, the physicians who treated the individuals with hemophilia, and the individuals with hemophilia.”⁹⁵ Consequently, “little incentive was available” to improve the safety of factor concentrates through the expeditious development of new technologies such as viral inactivation.⁹⁶

But in fact, viral inactivation methods *were* being researched. In the 1970s, every factor-concentrate manufacturer, unknown to the medical community and each in isolation from its competitors, conducted research into the possibility of using heat pasteurization to kill viruses in blood products. However, this process was not implemented by the blood manufacturers until well after the hepatitis epidemic had exacted its toll on hemophiliacs. It was only in the early 1980s, as it became clear that AIDS was a blood-borne disease, that the manufacturers of concentrated blood products applied for FDA licensing of heat-treatment processes.⁹⁷ Approval

factor concentrates in the face of a hemorrhage or to alter present replacement therapy regimens”).

94. The National Cancer Institute reported in a survey of 16 hemophilia care centers that 50% of hemophiliac patients were infected with HIV from 1978 to 1990. The rate of infection increased rapidly after 1978 and peaked at a rate of 22 infections per 100 person-years at risk in October 1982. See Barbara L. Kroner et al., *HIV-1 Infection Incidence Among Persons with Hemophilia in the United States and Western Europe, 1978-1990*, 7 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 279, 281 (1994).

95. IOM REPORT, *supra* note 25, at 82.

96. *Id.* Physical heat or chemical detergents can be used to inactivate viruses and other infectious agents in plasma products. There are, however, no effective methods of inactivating viruses in whole blood or non-plasma products (such as red blood cells and platelets) used in transfusions. Although some derivative blood products had been heat-treated since the late 1940s, Factor VIII and IX concentrates were not pasteurized until 1983 and 1984, respectively. See *id.* at 5, 81.

97. See *id.* at 94. All four major blood products manufacturers applied for FDA approval within a six-month period between June and December 1982. See *id.* at 92. The first application, by Baxter Healthcare, came 12 months after the first report of a cluster of *pneumocystis carinii* pneumonia (a common infection in HIV patients) in Los Angeles in June 1981, and five months after the Center for Disease Control learned of the first suspected case of AIDS (then called “Gay Related Immune Deficiency”) in a heterosexual hemophiliac. See *id.*

was quickly granted, and the techniques proved to be completely effective in preventing viral transmission.⁹⁸

These same methods, if implemented earlier, would have prevented the mass infection of hemophiliacs with HIV.⁹⁹ Moreover, they would have quashed the hepatitis epidemic among hemophiliacs. Although the hepatitis virus is more resistant to heat than HIV, both hepatitis C and HIV are effectively eradicated by heat pasteurization.¹⁰⁰ The prevalence of hepatitis among hemophiliacs had moved blood-products manufacturers to begin research into viral inactivation methods,¹⁰¹ but it was only the shock of the AIDS epidemic that caused them to move this research off the back burner and to implement pasteurization across the board.

The Institute of Medicine Report suggested that several factors contributed to the delay in bringing pasteurization techniques to market. First, there was the widespread sense of inevitability and resignation concerning hemophiliacs' vulnerability to hepatitis.¹⁰² Hepatitis was "viewed to be an acceptable risk for individuals with hemophilia because it was considered a medically manageable complication of a very effective treatment for hemophilia."¹⁰³ Second, the government, the medical community, and the blood fractionators did not seem to realize that other "new serious pathogens" might also be present in their untreated blood

98. A hemophiliac's risk of contracting HIV from concentrated blood products plummeted from 22 in 100 to less than 4 in 100 by July 1984, when heat-pasteurized blood products came on the market. No cases of HIV transmission have been reported among recipients of the virus-inactivated concentrates now in use. See Kroner, *supra* note 94, at 284; see also Roberts & Hoffman, *supra* note 8, at 1423 (noting that "[s]creening of donor populations and new techniques for preparing factor VIII concentrates since 1985 have essentially eliminated the risk of HIV transmission").

99. See IOM REPORT, *supra* note 25, at 82 ("[B]ecause the product treatment methods used to inactivate hepatitis viruses also inactivate HIV, their availability prior to 1981 would have minimized, if not prevented, the widespread HIV infection of persons with hemophilia."). Over 16,000 hemophiliacs in the United States were infected with HIV from blood products in the early 1980s. See *id.* at 1. According to one study, AIDS was the primary cause of 65% of the deaths in hemophilic patients between 1986 and 1991, while bleeding was responsible for only 5%. See Roberts & Hoffman, *supra* note 8, at 1423. Epidemic patterns of infection similar to those of the United States were observed in other advanced countries where concentrated blood products, imported principally from the American producers, were relied on for treatment of hemophiliacs. For a discussion of the epidemiology of AIDS in several industrialized countries, see the works collected in AIDS IN THE INDUSTRIALIZED DEMOCRACIES (David L. Kirp & Ronald Bayer eds., 1992).

100. See Menitove et al., *supra* note 26, at 1650-51. Hepatitis B may survive pasteurization. See *id.* at 1650 (noting that "two patients were reported to be infected with hepatitis B after receiving pasteurized . . . factor VIII concentrates").

101. The Institute of Medicine concluded that the "fact that the plasma fractionation industry was able to produce an inactivated product for license consideration concurrent with, and shortly after, the first reports of AIDS in individuals with hemophilia suggests that hepatitis infection (rather than AIDS) provided the major motivation for the ultimate development of viral inactivation methods." IOM REPORT, *supra* note 25, at 95.

102. See *id.* at 92-95.

103. *Id.* at 93.

products.¹⁰⁴ Third, the FDA failed actively to encourage the blood manufacturers to make their products safer.¹⁰⁵ Instead, the FDA passively “looked to industry to provide the specific direction for progress in viral inactivation.”¹⁰⁶

This complacency on the part of regulators and manufacturers proved disastrous because, as the Institute of Medicine reported, the blood-products industry was characterized by a competitive environment that inhibited the expeditious and concerted development of viral inactivation techniques. Manufacturers’ “interest in gaining competitive advantage and concerns over yield and cost” obstructed the free exchange of research information and so delayed the development of pasteurization techniques.¹⁰⁷ The blood industry in the United States was dominated by four players.¹⁰⁸ Although this high degree of concentration produced investments in research, it did not lead to early development of heat-treatment processes. The costs associated with heat-treatment methods, which required much higher levels of collection, deterred their implementation. Such inertia is not uncommon when a firm’s existing level of profitability is adequate and its technical expertise and finances are sufficient to respond if a competitor introduces a new product that threatens its competitors’ market share.¹⁰⁹ Had a tort remedy been available, the logjam might have been broken earlier, as litigation might have compelled the disclosure of the manufacturers’ substantial research into heat-treatment methods. As it was, however, the FDA passively deferred to the judgment of an industry whose economic interests and behavior mitigated *against* the rapid development of an alternative safer design for blood products. The lack of urgency about pursuing this research and development had deadly consequences for the hemophiliac users of those products.

B. Hepatitis, HIV, and the Blood Supply: A Challenge Ignored in the Restatement (Third)

The hepatitis and HIV epidemics among hemophiliacs illustrate the harm that can be caused by excluding blood products, prescription drugs, and other medical products from the ordinary rules of products liability. The epidemics struck in an environment insulated from liability concern—the remedy of design-defect review was essentially foreclosed both by

104. *Id.*

105. *See id.* at 94.

106. *Id.*

107. *Id.*

108. *See id.* at 92.

109. *See* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 842-50 (1988) (discussing the limitations of the profit-maximizing race model of commercial innovation).

statute and by the common law's tacit acceptance of the conventional wisdom that the dangers presented by blood products and other drugs were unavoidable. But it later was determined that they were not unavoidable; rather, there were practical and technically feasible alternative safer designs for blood products. If the alternative design test of section 2 had been applicable to the blood manufacturers during this period, courts might reasonably have concluded that the entire industry was negligent in its failure to develop and adopt alternative safer designs in a timely manner.

The lessons of the hepatitis and HIV epidemics were not heeded by the ALI. The *Restatement (Third)* instead maintained and ratified the insulation of blood products manufacturers from the ordinary rules of products liability, notwithstanding hemophiliacs' disastrous experience with concentrated blood products in the 1970s and 1980s. This exclusion was unchallenged at the ALI's annual meetings despite the Reporters' acknowledgment that blood products met the "formal requisites" for inclusion in the general law of products liability.¹¹⁰ The *Restatement (Third)* pointed to the states' broad legislative exclusions of blood products and blandly noted that "[w]here legislation has not addressed the problem, courts have concluded that strict liability is inappropriate for harm caused by such product contamination."¹¹¹

Because of the blood shield laws, hemophiliacs have had no tort remedy. The *Restatement (Third)*'s section 19(c) acquiesced in that result. The outcome would have been the same even if section 6(c)'s "net benefit" rule had been the law for blood products. The blood-products manufacturers would have won summary judgment in any design-defect case brought by an HIV- or hepatitis-infected hemophiliac, even though their contaminated products unnecessarily transmitted the deadly viruses. Under section 6(c), the manufacturers could have argued successfully that reasonable medical practitioners prescribed concentrated blood products because they provided a net benefit for hemophiliacs. They markedly extended the lives of these patients, albeit at the risk of chronic infection with hepatitis and HIV. Thus, the fractionated blood products satisfied section 6(c). In contrast, if the alternative-safer-design test of section 2 had been the rule, the blood manufacturers might well have been found liable for defective product design.

The history of litigation brought against factor-concentrate manufacturers illustrates the immense barriers that hemophiliacs have faced in obtaining compensation for hepatitis and HIV infections contracted from blood products.¹¹² Because of the blood shield laws and adverse common-

110. See RESTATEMENT (THIRD), *supra* note 1, § 19 cmt. c.

111. *Id.*

112. Hemophiliac victims of HIV may be able to obtain a limited amount of compensation from the federal government. The 1998 Ricky Ray Hemophilia Relief Fund Act provides for

law precedent, the prospects of success for plaintiffs in claims based on state tort law were poor.¹¹³ A federal class action, *Wadleigh v. Rhone-Poulenc Rorer, Inc.*,¹¹⁴ was brought in 1993. The plaintiffs alleged that the fractionators, who knew in the 1970s that viruses such as hepatitis were blood-borne, should have taken precautions to prevent viral contamination of their products.¹¹⁵ The fractionators used plasma collected from paid donors, a group they should have known contained many persons at high risk for viral infection, such as intravenous drug users. The plaintiffs claimed the fractionators were negligent in failing to use available technology to sterilize anti-hemophilic factor products when they knew that hemophiliacs were being infected with serious viral diseases from their products.¹¹⁶ The manufacturers defended on the basis that the HIV virus was "unknown and unforeseeable during any period of the time defendants were not taking the precautions plaintiffs claim they should have been

"compassionate payments" to HIV-infected hemophiliacs (and their survivors) who received concentrated blood products from proprietary manufacturers in the period from July 1, 1982 (when the first three cases of immune suppressive disorder were identified in hemophiliacs) to December 31, 1987 (by which time all unpasteurized blood product stocks had been exhausted or destroyed). See 42 U.S.C.A. § 300c-22 (West Supp. 1999). However, Congress still has not funded the program. See Ricky Ray Hemophilia Relief Fund Act of 1998, Procedures for Filing Petitions for Payment, 69 Fed. Reg. 14,251 (1999). Prior to the Act's passage, American hemophiliacs were alone among hemophiliacs in the advanced countries in having been offered no government compensation. For a discussion of governmental compensation schemes in several industrialized nations, see generally the works collected in AIDS IN THE INDUSTRIALIZED DEMOCRACIES, *supra* note 99.

113. See, e.g., *Doe v. Miles Lab.*, 927 F.2d 187, 192-94 (4th Cir. 1991) (holding that a clotting agent's benefits to patients suffering from uncontrolled bleeding precluded plaintiff's strict-liability action as well as plaintiff's negligence claim for failure to screen blood donors); *McKee v. Cutter Lab.*, 866 F.2d 219, 221-22 (6th Cir. 1989) (finding that plaintiff's strict-liability claims against a factor-concentrate manufacturer were barred by Kentucky's blood shield statute); *Coffee v. Cutter Biological*, 809 F.2d 191, 193-95 (2d Cir. 1987) (holding that the HIV-infected hemophiliac plaintiff's claim was barred by Connecticut's blood shield law); *Hyland Therapeutics v. Superior Court*, 175 Cal. App. 3d 509, 516 (Ct. App. 1985) ("[L]egislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally."); *Rogers v. Miles Lab.*, 802 P.2d 1346, 1350-52 (Wash. 1991) (holding that common-law strict liability was not available for claims against blood-products manufacturers because the doctrine's effect "would be that a product, essential to sustain the life of some individuals, would not be available").

114. 157 F.R.D. 410 (N.D. Ill. 1994). The other major manufacturers of fractionated blood products, Armour Pharmaceutical Co., Miles, Inc., Baxter Healthcare Corp., and Alpha Therapeutic Corp., were codefendants in the case, as was the National Hemophilia Foundation. See *id.* The plaintiffs alleged that the National Hemophilia Foundation, influenced by financial contributions from the fractionators, had given unfounded assurances of the safety of the fractionators' products, knowing that hemophiliacs and their physicians would rely on those assurances. See *id.* at 414. *Wadleigh* was consolidated in the Northern District of Illinois in multidistrict litigation managed by Judge John Grady. See *In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 169 F.R.D. 632 (N.D. Ill. 1996).

115. See *Wadleigh*, 157 F.R.D. at 414.

116. See *id.*

taking” and that they began heat pasteurization as soon as they were technologically and legally able to do so.¹¹⁷

In 1995, the Seventh Circuit decertified the plaintiff class.¹¹⁸ Chief Judge Posner disparaged the plaintiffs’ theory “that before anyone had heard of AIDS or HIV, it was known that Hepatitis B, a lethal disease though less so than HIV-AIDS, could be transmitted either through blood transfusions or through injection of blood solids”¹¹⁹ and their argument that “due care with respect to the risk of infection with Hepatitis B required the defendants to take measures to purge that virus from their blood solids, whether by treating the blood they bought or by screening the donors.”¹²⁰ The court fretted that a single adverse jury verdict might bankrupt the defendants, and that the defendants might feel compelled to agree to a large settlement despite the lack of any proper basis for liability.¹²¹ The case was remanded for “a decentralized process of multiple trials.”¹²² In April 1996, the defendants made a joint offer to settle the claim of each infected hemophiliac who had used their products, as well as the claims of persons who had become infected by reason of specified relationships with those persons. The final settlement was small—each plaintiff received a net cash payment of \$100,000.¹²³

The *Rhone-Poulenc Rorer* case exemplifies the hobbling effect of the blood shield laws and immunizing rules such as sections 6(c) and 19(c) on litigation by persons injured by defective blood products. Section 6(c), of course, has the same effect on design-defect claims against makers of medical devices, prescription drugs, and vaccines. Under these rules, even if potential plaintiffs prove the existence of a reasonable alternative safer design, the manufacturers can evade liability if they can demonstrate a net benefit of the product to at least one class of users. Section 6(c) would not permit, for example, a challenge to a live-virus vaccine that unnecessarily caused the disease it was designed to prevent, even if there had long been an equally effective killed-virus vaccine that does not cause infection. These products are quite amenable to judicial review under the section 2 defect standard.

The choice between the Sabin live-attenuated-virus oral polio vaccine (OPV) and the Salk killed-virus injected polio vaccine (IPV) presents a

117. *In re Factor VIII*, 169 F.R.D. at 633-34.

118. *See In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1304 (7th Cir. 1995).

119. *Id.* at 1296.

120. *Id.*

121. *See id.* at 1298.

122. *Id.* at 1299.

123. *See In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 169 F.R.D. 632, 634 (N.D. Ill. 1996). The settlement approximated market share: Bayer paid 45%, Alpha 15%, and Armour and Baxter 20% each. *See Blood Product Firms To Pay Government \$12 Million To Settle Health Care Claims*, 6 Health L. Rep. (BNA) 712, 712 (May 5, 1997).

concrete case in which the reasonableness of a design choice can be tested using the alternative-safer-design test. OPV virtually eradicated the polio epidemic in the United States within a few years of its introduction.¹²⁴ However, because it contains live polio viruses, OPV sometimes caused vaccinees to develop Vaccine Associated Paralytic Polio (VAPP). Persons who are immunocompromised are particularly susceptible to developing VAPP. The virus can infect not only vaccinees, but also persons in close contact with them. Of the 133 reported cases of polio in the United States in the 1980-1994 period, 125 were VAPP cases.¹²⁵ At present, the risk of contracting VAPP from an OPV vaccination is about one case in 2.4 million doses distributed.¹²⁶ This risk translates into eight or nine OPV cases per year.¹²⁷

Enhanced-potency IPV, an alternative design of the polio vaccine that does not use live polio virus, was developed in 1978. Enhanced IPV is as effective as OPV in preventing polio but cannot itself cause the disease.¹²⁸ France, Finland, Sweden, and the Netherlands have eliminated polio by relying exclusively on IPV.¹²⁹ The United States has been slow to change, but in 1999 the Centers for Disease Control recommended complete reliance on IPV.¹³⁰

The question for products-liability law is whether the risk associated with OPV can be justified in light of the availability of an alternative safer design, the enhanced-potency IPV. In making this determination, both the reduction of VAPP risk achievable through IPV and the relative effectiveness of the two vaccine designs in preventing polio should be considered. Since research has demonstrated conclusively that IPV and OPV are equally effective in preventing the disease, the clear choice under this test is IPV. There is thus a strong argument that the availability of IPV has rendered OPV unreasonably unsafe, despite the enormous social utility of OPV.

In urging that the United States move toward an IPV-only vaccination regime, the Centers for Disease Control sought an optimal product design.

124. In the early 1950s, approximately 50,000 cases of polio per year were identified in the United States. By 1969, only about a dozen cases were recorded. See Joseph L. Melnick, *Live Attenuated Polio Virus Vaccines*, in VACCINES 155, 187 tbl.7-17 (Stanley A. Plotkin & Edward A. Mortimer eds., 2d ed. 1994).

125. See Centers for Disease Control & Prevention, *Poliomyelitis Prevention in the United States*, MORBIDITY & MORTALITY WKLY. REP., Jan. 24, 1997, at 5 (recommendations of the Advisory Committee on Immunization Practices); Frederick C. Robbins, *Polio—Historical*, in VACCINES, *supra* note 124, at 137, 141-42.

126. See Centers for Disease Control & Prevention, *supra* note 125, at 6.

127. See *id.* at 2.

128. See Centers for Disease Control & Prevention, *supra* note 125, at 7-8; Jonas Salk et al., *Noninfectious Poliovirus Vaccine*, in VACCINES, *supra* note 124, at 216-17, 219, 222.

129. See Centers for Disease Control & Prevention, *supra* note 125, at 1-2, 8.

130. See Marlene Cmons, *End Oral Polio Vaccine, Panel Says*, L.A. TIMES, June 18, 1999, at A26.

The risk-benefit analysis it undertook closely tracked the analysis of tort law, weighing the benefits, costs, and risks of the proposed heightened safety precaution.¹³¹ However, the regulators and vaccine manufacturers might justly be faulted by a person infected with VAPP for waiting to recommend the exclusive use of IPV until sixteen years after France made that change.

Under a section 2 alternative-safer-design analysis, OPV would be deemed a defective product and the manufacturers of OPV thus could be held liable for VAPP injuries caused by their product. But under a section 6(c) analysis, these manufacturers would not be held liable. Although IPV is an entirely reasonable and much safer alternative design, the section 6(c) defect test would deem the use of OPV reasonable because the OPV vaccine has a net benefit for its users.¹³² Because it is effective in preventing polio in the population and causes the disease in only a small percentage of cases, in the aggregate the vaccine does more good than harm. However, the existence of an equally effective safer alternative design makes the risk of serious injury, however small, an unreasonable risk. That OPV has a high social utility should be irrelevant to the question of whether it was unreasonable not to move more quickly to the safer alternative design. Application of the section 2 defect standard would achieve the more just result in adjudicating VAPP claims.

Those who would rely on the market, the FDA, and "learned intermediaries" such as physicians to assure the safety of medical products should consider seriously the lessons of our experience with the blood supply. The catastrophic experience of hemophiliacs with hepatitis and HIV, as well as other problems such as polio vaccine-related disease, should prompt us to ask several questions: Should drugs, blood products, vaccines, and medical devices be treated differently by the law than trains, planes, and automobiles? Should the blood shield laws be repealed as outmoded and unduly protective of manufacturers who sell products reasonably capable of being made safer?

131. See Centers for Disease Control & Prevention, *General Recommendations on Immunization*, MORBIDITY & MORTALITY WKLY. REP., Jan. 28, 1994, at 1-38.

132. OPV satisfies the net benefit test, notwithstanding the fact that IPV is equally effective and safer because it cannot cause VAPP. The American Academy of Pediatrics, which still advocates OPV as the vaccine of choice, has since 1991 maintained that both IPV and OPV are "effective in preventing poliomyelitis," and that IPV should be offered to "individuals who have refused OPV or in whom OPV is contraindicated"—for example, persons with compromised immunity and children who have close contact with adults who have not been immunized against polio. Salk, *supra* note 128, at 222. The World Health Organization "prefers the use of OPV because of its low cost, ease of administration in mass campaigns, superiority in conferring intestinal immunity, and ability to infect household and community contacts" with the vaccine virus. *Id.* at 221. It should be noted that OPV's superiority in conferring intestinal immunity is disputed. See *id.* at 220. Additionally, while infection of household and community contacts with the vaccine virus can serve an immunizing function, it can also cause vaccine-associated paralytic disease in those persons. *Id.* at 220-21.

The fundamental functions of the tort system are to identify socially unreasonable conduct and to compensate the victims of such conduct:

The issue in every products case is whether the product *qua* product meets society's standards of acceptability[;] . . . [w]hether . . . we as a society will live with it in its existing state or will require an altered, less dangerous form. Stated succinctly, the question is whether the product is a reasonable one given the reality of its use in contemporary society.¹³³

By that measure, the categorical exclusion of blood and blood products from the generally applicable rules of products-liability law has failed. It has exempted vital products from having to answer the basic question of reasonableness. The *Restatement (Third)* as a whole reflects the law's movement toward measuring reasonableness of product designs in terms of the availability of an alternative safer design.¹³⁴ If the blood-products manufacturers had been included in this movement, rather than placed behind a legislative shield, the alternative safer designs for blood products that were implemented when AIDS appeared (but largely developed in the languid days of the hepatitis epidemic) might have seen the light of day years earlier. Those products—practical and feasible from a technological standpoint, but unavailable due to business decisions—might have saved 8000 lives in the United States, and more abroad. Even if the manufacturers had not been persuaded by the liability regime to adopt the safer product design earlier, at least the victims of their defective products would have had better prospects of obtaining compensation through the tort system.

Section 402A of the *Restatement (Second)* was the foundation for the development of products-liability law in the last thirty years. It freed the courts from unreasonably burdensome proof requirements and constricting doctrines such as privity. Section 402A greatly boosted the incipient movement toward strict liability for defective products, a development of which the ALI may be justly proud, notwithstanding the doctrinal confusion in the courts between negligence and strict liability. Now, unfortunately, at a time when demographics and dollars guarantee that health care issues will be at the forefront, the ALI has adopted a new medical products design-defect rule that spurns these gains. The *Restatement (Third)*'s section 6(c) points in the wrong direction, asking less, rather than more, of those who design, manufacture, and sell the products of our increasingly powerful medical technologies.

133. William A. Donaher et al., *The Technological Expert in Products Liability Litigation*, 52 TEX. L. REV. 1303, 1307 (1974). Professor Twerski was a coauthor of this article.

134. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. d Reporter's note.

IV. RESTORING COHERENCE TO THE LAW OF PRODUCTS LIABILITY: CLOSING THE GAP BETWEEN MEDICAL AND OTHER PRODUCTS

A. *Restating the Restatement: Reconciling the Lines*

The epidemics discussed above demonstrate the aptness of tort-system review of drug product safety. The questions raised by the epidemics—for example, when could safer techniques reasonably have been demanded of blood products manufacturers?—boil down to the fundamental moral questions in all tort litigation: Who blundered? Was the loss wrongful? Despite critics' assertions to the contrary,¹³⁵ these issues are amenable to adjudication by juries and judges. They demand less technical expertise than they do reasoned judgment and reference to norms of right and justice.

It is the thesis of this Essay that prescription drugs, blood products, vaccines, and medical devices should be subject to the same standards of design-defect review as other products, and that the approach taken to determine liability by section 2 of the *Restatement (Third)* is adequate to the task. Underlying the preference for the section 2 standard is the view that the section 6(c) standard sends the wrong message. It abandons the safety-advancing objectives of products-liability law and lets the burden of loss fall on persons whose suffering could have been reduced or avoided by practical, feasible, and reasonably available alternative safer product designs.

The essential ground on which the existing body of the law of medical products liability should be restated is this: If the evidence shows that the challenged product could have been designed more safely without substantially impairing its effectiveness for indicated uses, or that there existed another drug or device of equivalent effectiveness for all indicated uses but with significantly greater safety, the product should be analyzed as are other products under section 2(b). The fundamental comparisons to be made involve the nature and extent of the reduction of harm from the adoption of the alternative design, the impact on product effectiveness, and the cost, practicality, and feasibility of making the design change.

When at the time of sale there existed no reasonable, practical, and available safer-design choice and no other substitute product, then a "manifestly unreasonable design" standard¹³⁶ should be applied. In that situation, the challenged product's aggregate utility for its indicated uses should be weighed against the product's known risks at the time of sale to

135. See, e.g., Henderson, *supra* note 78, at 495 ("[P]rescription drugs present quite different product design issues, unique unto themselves and clearly beyond the institutional competence of courts to manage.").

136. The "manifestly unreasonable design" test currently is embodied in a comment to section 2 of the *Restatement (Third)*. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. c.

determine whether a reasonable manufacturer would have sold the product at all. If the drug product or medical device is shown to be of such little utility compared to its hazards that a reasonable person would not have marketed the product at all, it will be found defective under the “manifestly unreasonable design” standard of section 2. Products that have no alternative safer design or substitute product remain subject to review under section 2(c) for the adequacy of their warnings and instructions.

B. *The Place of Fault in the Law of Drug and Medical Device Design Liability*

This proposed revision reconciles the two lines of cases from the era of comment *k*, the *Brown* line and the *Feldman-Kearl-Toner* line. These two common-law strands shared a negligence-based core. Negligence is the main thrust of design-defect analysis in the *Restatement (Third)*: Section 2(b) establishes that in order for a product to be found defective, the harm must have been reasonably preventable.¹³⁷ Under the alternative-safer-design test, a manufacturer’s failure to take reasonable precautions against injury is negligent regardless of the overall utility of the product.¹³⁸ As we have seen, this functional approach is capable of accommodating defect claims involving *all* types of products, including single and combination drugs, vaccines, blood products, and medical devices. The exclusion of medical products from section 6(c) is unnecessary and undermines the *Restatement*’s integrity.

Leading critics of the strict-liability movement had long argued that a negligence-based standard was appropriate for drugs,¹³⁹ but the Reporters rejected that approach. They declared before the ALI process even began that “courts should not review the adequacy of prescription drug

137. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. f.

138. See Green, *supra* note 67, at 619. Green asks:

What of the utility of the product? Irrelevant to the analysis. What we are interested in is the marginal utility of the existing design, not the overall societal benefits of the product. To put the point another way, imagine that we have identified a one hundred percent effective vaccine for AIDS. Suppose the vaccine causes a mild auto-immune reaction—a rash that lasts for a week—in one out of a million persons who take the vaccine. The side effect can be eliminated by changing one of the inert ingredients with which the vaccine is coated to another inert ingredient, no more expensive and equally adept at serving its purpose. The vaccine is defectively designed despite its enormous social utility. Risk-benefit analysis operates at the margin—the utility of the existing design compared to the alternative—not at the level of the entire product.

Id.; see also John W. Wade, *On Product “Design Defects” and Their Actionability*, 33 VAND. L. REV. 551, 572 (1980) (commenting that the *Barker* court’s language should “make clear to the jury that it is to look primarily to the utility or benefit of that aspect of the design which is claimed to be improper or ‘defective’ rather than to the utility or benefit of the product in general”).

139. See, e.g., Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1141 (1985).

designs.”¹⁴⁰ The *Restatement (Third)*’s exclusion of medical products from its section 2 rule was driven by the view, expressed by Professor Henderson, that a “wide-open negligence approach” to drug-design review was unwarranted absent evidence of massive failure of the FDA regulatory process or of the system of physician control of drugs via prescription.¹⁴¹ But the experience of the hemophiliacs, as well as instances of physicians overprescribing certain drugs despite uncertainty about their safety and efficacy,¹⁴² shows that both types of failure have occurred. The responsibility for such epidemics may be shared by regulators, physicians, manufacturers, and even some patients.¹⁴³ However, that does not provide a rationale for near-immunity for manufacturers, particularly in a system in which comparative negligence principles provide a ready means of allocating fault.

The fault-based approach to drug products liability has deep roots in the *Restatement (Second)*. By using the term “unavoidably unsafe,” comment *k* showed that the section 402A strict-liability doctrine had a negligence core, because the imposition of liability required that somewhere in the design or manufacturing process, someone have had a “fair chance” to avoid the harm.¹⁴⁴ The *Restatement (Third)* departs from that fault-based approach by providing that, in the case of prescription medical products, reasonably

140. Henderson & Twerski, *supra* note 14, at 1536.

141. See Henderson, *supra* note 78, at 483, 494.

142. Calcium antagonists used to treat hypertension, such as nifedipine, are one example. See Curt D. Furberg et al., *Nifedipine: Dose-Related Increase in Mortality in Patients with Coronary Heart Disease*, 92 CIRCULATION 1326, 1326 (1995) (finding that the use of nifedipine in moderate to high doses increases the mortality rate of patients with coronary disease and postulating that “[o]ther calcium antagonists may have similar adverse effects”); Teri A. Manolio et al., *Trends in Pharmacologic Management of Hypertension in the United States*, 155 ARCHIVES INTERNAL MED. 829, 829 (1995) (noting that the “[u]se of calcium antagonists and angiotensin-converting enzyme inhibitors in hypertension has increased dramatically in the past 10 years” despite a lack of evidence of the effectiveness of these drugs). Such data prompted federal health officials to issue alerts in an attempt to change the pattern of prescriptions by physicians. See Lawrence K. Altman, *Risk of Death Found in Use of Heart Drug*, N.Y. TIMES, Nov. 1, 1995, at A16. The overprescribing of nifedipine is of concern not only because of its health implications, but also because of the high cost of the drug. See Manolio et al., *supra*, at 829 (calculating that the increase in the number of nifedipine prescriptions over the 1982-1992 period resulted in an additional \$3.1 billion in expenditures nationwide).

143. Patients, however, generally have limited choice in the physician-dominated health care environment.

144. This idea was famously expressed in OLIVER WENDELL HOLMES, *THE COMMON LAW* (Mark DeWolfe Howe ed., 1963) (1881):

The true explanation of the reference of liability to a moral standard, in the sense which has been explained, is not that it is for the purpose of improving men’s hearts, but that it is to give a man a fair chance to avoid doing the harm before he is held responsible for it. It is intended to reconcile the policy of letting accidents lie where they fall, and the reasonable freedom of others with the protection of the individual from injury.

Id. at 115. This concept of preventable harm is also present in the *Restatement (Third)*’s section 2(b) alternative design rule. See RESTATEMENT (THIRD), *supra* note 1, § 2 cmt. f (referring to “the commonsense notion that liability for harm caused by product designs should attach only when harm is reasonably preventable”).

avoidable harm will not be the basis for liability except where the product's risks as a whole outweigh its dangers.

In support of this rule, the Reporters drew most heavily on the 1988 *Brown v. Superior Court* decision. But the court in that case actually acknowledged the possibility of redesign of the carcinogenic anti-miscarriage drug DES.¹⁴⁵ The *Brown* court nonetheless rejected the usual form of risk-utility analysis, as set forth in *Barker v. Lull Engineering Co.*¹⁴⁶ The *Brown* court explained:

[T]here is an important distinction between prescription drugs and other products such as construction machinery, a lawnmower, or perfume, the producers of which were held strictly liable. In the latter cases, the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use.¹⁴⁷

The *Brown* court expressed a fear that useful products would be driven from the market, either by juries sympathetically identifying with the injured plaintiff¹⁴⁸ or by courts engaging in crude risk-benefit calculations that had already been performed by a presumably more competent regulator, the Food and Drug Administration.¹⁴⁹

145. Justice Mosk wrote:

We agree with defendants that *Barker* contemplates a safer alternative design is possible, but we seriously doubt their claim that a drug like DES cannot be "redesigned" to make it safer. For example, plaintiff might be able to demonstrate at trial that a particular component of DES rendered it unsafe as a miscarriage preventative and that removal of that component would not have affected the efficacy of the drug. Even if the resulting product, without the damaging component, would bear a name other than DES, it would do no violence to semantics to view it as a "redesign" of DES.

Brown v. Superior Court, 751 P.2d 470, 478 (Cal. 1988).

146. 573 P.2d 443 (Cal. 1978).

147. *Brown*, 751 P.2d at 478-79 (citation omitted).

148. How much power remains in that argument is debatable. See, e.g., *DeHanes v. Rothman*, 727 A.2d 8, 12-13 (N.J. 1999) (citing survey evidence indicating that jurors believe liability suits increase their own costs as consumers and deeply mistrust civil litigants and paid expert witnesses).

149. See W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437 (1994). Viscusi and his coauthors argue that

laissez faire pharmaceutical litigation often creates perverse incentives. These incentive effects can lessen the value or even countermand the judgments of the FDA, thereby overturning the agency's well-considered risk-benefit assessments. Because a fully

Pharmaceutical manufacturers welcomed the *Brown* decision. They understandably had viewed with alarm the emerging trend toward strict products-liability law, and they did not wish to share the label "toxic torts" with products like asbestos. But by the time *Brown* was decided, the tide had already fallen from the high-water mark of strict-liability jurisprudence. That zenith was represented by the New Jersey Supreme Court's holding in *Beshada v. Johns-Manville Products Corp.*,¹⁵⁰ an asbestos case, that liability would be imposed even for unknowable hazards.

The *Beshada* court adopted a dual standard of product defect. It first inquired into whether the product's utility outweighed its risk. If not, the court deemed the product "not reasonably fit for its intended purposes" and imposed strict liability for the injuries it caused.¹⁵¹ If so, the court proceeded to ask whether that risk had been reduced "to the greatest extent possible consistent with the product's utility."¹⁵² This second prong examines whether "the same product could have been made or marketed more safely" through an alternative design.¹⁵³

The asbestos producers in *Beshada* defended on the ground that "the danger of which they failed to warn was undiscovered at the time the product was marketed and . . . undiscoverable given the state of scientific knowledge" at the time of sale.¹⁵⁴ The court accepted these assertions as true, for the sake of argument, but rejected the defense of unknowability:

The imputation of knowledge is, of course, a legal fiction. It is another way of saying that for purposes of strict liability the defendant's knowledge of the danger is irrelevant. The imputation of knowledge does not represent any presumption that defendants

informed FDA almost certainly makes erroneous risk-benefit judgments less often than our tort system, the role of tort law in this context needs to be refocused.

Id. at 1475.

150. 447 A.2d 539 (N.J. 1982); *see also* Henderson & Twerski, *supra* note 2, at 1271 ("Decisions published during the late 1970s and early 1980s represent what many observers consider to be the high water marks of this expansionary, remarkably proplaintiff period."). The *Beshada* decision was widely criticized by academic commentators. The *Feldman v. Lederle Laboratories* opinion, 479 A.2d 374, 388 (N.J. 1984), cites a number of these criticisms, including Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 877-82 (1983); Victor Schwartz, *The Post-Sale Duty To Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. REV. 892, 901-05 (1983); John W. Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 754-56 (1983); Robert D. Casale, Comment, *Beshada v. Johns-Manville Products Corp.: Adding Uncertainty to Injury*, 35 RUTGERS L. REV. 982, 1008-15 (1983); William R. Murray, Jr., Comment, *Requiring Omniscience: The Duty To Warn of Scientifically Undiscoverable Product Defects*, 71 GEO. L.J. 1635 (1983); and Robert D. Towry, Note, 13 SETON HALL L. REV. 625 (1983).

151. *Beshada*, 447 A.2d at 545.

152. *Id.*

153. *Id.*

154. *Id.* at 542.

knew or even that they could have known of the product's dangers.¹⁵⁵

The pharmaceutical industry was alarmed by *Beshada*'s assertion that the state of knowledge at the time of manufacture was irrelevant. However, *Beshada* was quickly followed by the New Jersey Supreme Court's declaration, in *Feldman v. Lederle Laboratories*, that the *Beshada* standard of liability was to be limited to asbestos cases.¹⁵⁶ The *Feldman* court also rejected the invitation by the defendant, Lederle, and a host of pharmaceutical industry organizations to rule that prescription medicines should be categorically exempted from the ordinary rules of design-defect review and strict liability for defective products.¹⁵⁷ It decided to treat drugs like other products—that is, to subject drugs to the risk-utility weighing prescribed by Wade.¹⁵⁸ Wade's formulation had been incorporated verbatim into New Jersey's Model Civil Jury Charges.¹⁵⁹

The *Feldman* decision embraced Wade's "time of distribution" test of constructive knowledge of danger¹⁶⁰ and laid the foundation for a fault-based regime governing defects in drug design. *Feldman* restated the New Jersey Supreme Court's long-held view that the test of defectiveness is two-pronged: One asks, first, whether the product as a whole does more good than harm (the per se negligent marketing test) and, second, if so, whether the manufacturer has reduced the risks of the product to the greatest extent possible. The court thus approached drug-design review with the same fault-based concepts that had constituted the dominant doctrines of design-defect liability since the wholesale adoption of the Wade risk-utility balancing test in 1978.¹⁶¹

Victor Schwartz, the influential author, practitioner, and lobbyist, praised *Feldman*'s rule that liability would not be imposed for defective drug designs when a risk of harm was unknown at the time of

155. *Id.* at 544 n.3 (citation omitted).

156. *See Feldman v. Lederle Lab.*, 479 A.2d 374, 388 (N.J. 1984).

157. *See id.* at 380 ("We do not agree that the protective shield of comment *k* immunizes all prescription drugs. Moreover, we are of the opinion that generally the principle of strict liability is applicable to manufacturers of prescription drugs.").

158. *See Wade*, *supra* note 2, at 837-38.

159. *See* George W. Conk, *Compared to What? Instructing the Jury on Product Defect Under the Products Liability Act and the Third Restatement of Torts: Products Liability*, 30 SETON HALL L. REV. 273, 275 (1999).

160. *See* John E. Keefe & Richard C. Henke, *Presumed Knowledge of Danger: Legal Fiction Gone Awry?*, 19 SETON HALL L. REV. 174, 185-86 (1989). Unlike Keeton, who argued that it was the state of knowledge of danger at the time of trial that determined liability, Wade had long argued that liability was limited to dangers that were scientifically knowable at the time of marketing. *See id.* at 180 & n.39.

161. *See Cepeda v. Cumberland Eng'g Co.*, 386 A.2d 816, 826-27 (N.J. 1978).

manufacture.¹⁶² Schwartz argued against strict liability and in favor of a safety-advancing negligence standard in cases involving pharmaceutical products:¹⁶³

The basic message here is that, in general, ethical drugs and harms that arise out of their use should not subject their manufacturer, distributor or retailer to strict liability. Society wishes to encourage the manufacture of ethical drugs, and the research and development of new drugs. . . .

. . . If [however] an ethical drug, in light of the state of human knowledge at the time of manufacture, can be made safe for its intended and ordinary use, the manufacturer is to meet that standard.¹⁶⁴

Schwartz recognized, as Prosser had, that comment *k* could be read as infusing the entire law of design defect with a fault-based essence. He noted that the courts' distinction between drugs and other products was a function not of any explicit mandate in comment *k*, but rather of the absence, in that comment, of any examples other than pharmaceuticals.¹⁶⁵ He concluded that "[f]or this reason the courts and most commentators have assumed that comment *k* relates to pharmaceuticals and this assumption as a *practical matter* appears to be correct."¹⁶⁶ Thus, in Schwartz's view, the "drugs are different" approach was an accurate description of how the courts had construed comment *k* up to that point, but was not the only reasonable interpretation of comment *k*. While Schwartz did not go a step further and explicitly affirm the amenability of both medical devices and at least some drugs (such as vaccines and processed blood products) to alternative-design-centered risk-utility analysis, he did recognize the doctrinal inadequacy of the common-law bifurcation of design-defect law.

Schwartz argued that in a negligence-based products-liability regime, the standard of care owed by manufacturers need not be diluted for pharmaceutical manufacturers. While it frequently had been argued that public policy considerations—for example, the concern that drug companies be encouraged to innovate and bring new medicines rapidly to market—militated in favor of greater insulation of drug manufacturers from liability, Schwartz observed that there might also be policy reasons to hold such manufacturers to "the very *highest* of standards":

162. See Schwartz, *supra* note 139, at 1145. Schwartz's article was cited approvingly both by the Idaho Supreme Court in *Toner v. Lederle Laboratories*, 732 P.2d 297, 305 (Idaho 1987), and by the California Supreme Court in *Brown v. Superior Court*, 751 P.2d 470, 475-76 (Cal. 1988).

163. See Schwartz, *supra* note 139, at 1139.

164. *Id.* at 1141.

165. See *id.*

166. *Id.* at 1141 (citing *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87 (2d Cir. 1980)).

The circumstances in which pharmaceutical manufacturers must deal directly involve severe risks to human life. Thus, their standard of care is not the “reasonableness” of a person who repairs a television set or drives a car—it is the most serious and intense obligation that one can find in the entire body of negligence law.¹⁶⁷

The California Supreme Court cited Schwartz’s article in its *Brown* opinion,¹⁶⁸ but unfortunately failed to understand Schwartz’s point. Despite its nod toward “general principles of negligence,”¹⁶⁹ *Brown* is a confused opinion. The court became tangled in its efforts to reconcile the fault-free rhetoric of its opinions in *Escola v. Coca Cola Bottling*,¹⁷⁰ *Greenman v. Yuba Power Products*,¹⁷¹ and *Cronin v. J.B.E. Olson Corp.*,¹⁷² with the fault-based risk-utility balancing in *Barker v. Lull Engineering Co.*¹⁷³ The incoherence that the Reporters later attributed to comment *k* is not that of the case law as a whole, which, as we have seen, generally follows the furrows of the rest of the field. The unintelligibility of which the Reporters complained is rooted in the *Brown* decision, upon which they relied.

The *Brown* court rejected strict liability while claiming to preserve the possibility of a negligence-based review for defects in drug design.¹⁷⁴ Yet the court held its negligence-based *Barker* risk-utility analysis inappropriate for drug-defect claims, mischaracterizing it as a strict-liability standard. Like many modern products-liability cases, the *Barker* decision contains strict-liability language but is actually a negligence-based liability analysis. The *Barker* risk-utility factors clearly were derived from the classic formulation of negligence by Judge Learned Hand in *United States v. Carroll Towing Co.*¹⁷⁵ The simultaneous embrace of “general negligence principles” and rejection of *Barker*’s risk-utility analysis brought doctrinal

167. *Id.* at 1145.

168. See *Brown v. Superior Court*, 751 P.2d 470, 475-76 (Cal. 1988).

169. *Id.* at 483 n.12.

170. 150 P.2d 436 (Cal. 1944) (Traynor, J., concurring) (advocating the adoption of strict liability for product defects).

171. 377 P.2d 897 (Cal. 1962) (applying strict liability where the plaintiff injured himself with a power tool).

172. 501 P.2d 1153 (Cal. 1972) (applying strict liability where the plaintiff was injured when an aluminum safety hasp broke).

173. 573 P.2d 443 (Cal. 1978); see also *Brown*, 751 P.2d at 477 (explaining *Barker*).

174. *Brown*, 751 P.2d at 482-83 (“[W]e hold that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.”).

175. 159 F.2d 169, 173 (2d Cir. 1947); see also *Barker*, 573 P.2d at 455 (adopting a five-factor design-defect test). Hand’s formula for negligence states that if the probability of injury (*P*) multiplied by the magnitude of injury (*L*) was greater than the burden on the manufacturer (*B*) of taking additional measures to avoid the injury (in other words, if $PL > B$), then the manufacturer is negligent. See *Carroll Towing*, 159 F.2d at 173. Though a negligence case, *Carroll Towing* also formed the basis for Wade’s enormously influential 1973 article describing his risk-utility analysis for products-liability litigation. See Wade, *supra* note 2.

incoherence to the *Brown* decision. The case consequently came to stand for immunizing drug manufacturers even when they designed avoidably unsafe products. The key omission in *Brown* is the court's failure to adopt Schwartz's approach, which, using negligence terms, imposed a high duty of care on pharmaceutical manufacturers. *Brown* does not hold pharmaceutical manufacturers to the standard of care for reasonable persons in like circumstances. The final, casual affirmation in the *Brown* opinion of negligence as a standard¹⁷⁶ is too weak to repair the damage done by the repudiation of the *Barker* risk-utility analysis. *Brown* is the intellectual source of the section 6(c) rule, which brings incoherence rather than consistency to the law of products liability.

Justice Mosk's justifications in *Brown* for setting drugs apart—that drugs “alleviate pain and suffering or . . . sustain life” and that “harm to some users from prescription drugs is unavoidable”¹⁷⁷—could be said of many kinds of products.¹⁷⁸ To conclude that a product deserves immunity from liability, the factual determination must be made that its dangers are in fact “unavoidable.” Harm preventable by reasonable care or by reliance on practical, feasible, and available alternative designs is not “unavoidable,” and manufacturers should be held responsible for failing to prevent such harms. Product designs that omit such choices do not deserve the same protection from liability as products that alleviate pain and suffering and for which there truly is no other, safer-design choice. The solution is to treat “all products alike rather than trying to distinguish before the fact the good or acceptably dangerous products (that get special treatment) from all other products (that get no special treatment).”¹⁷⁹

It also has been argued that the *Brown* court's finding that prescription drugs do greater good than other kinds of products, while it has a strong rhetorical ring, does not withstand scrutiny:

[I]t is a relatively short step from health-care products to other products that improve our quality of living and, by so doing, alleviate or prevent physical pain and suffering or save lives. . . . Prosser was right. There is no elegant way to distinguish between prescription drugs, all drugs, and other products such as “hair dye and shaving lotion.” . . . Following the logic of the above, the next step should be to apply the risk-benefit analysis of *Brown* [which suggests that negligence should govern] to all products liability cases. We would then have come full circle. Products liability would have been created initially as something

176. See *Brown*, 751 P.2d at 483 n.12.

177. *Id.* at 478.

178. See J. Clark Kelso, *Brown v. Abbott Laboratories and Strict Products Liability*, 20 PAC. L.J. 1, 26-28 (1988).

179. *Id.* at 26.

distinct from negligence and warranty but would have ended up being recognized as the same as negligence and warranty.¹⁸⁰

There are many reasons, therefore, to doubt the wisdom of the Reporters' decision to carve out special liability rules for medical products. In the final analysis, it is unexplained why such useful products as microchips, personal computers, telephones, trains, planes, and automobiles should always come in second to medical products in the calculus of social good. Moreover, why should things that we hope will bring us pleasure be subject to a more stringent standard of products liability than products that we hope will restore or maintain our health? Why should we ask less of those who make prescription drugs than we do of makers of other useful goods?

C. *The Rationales for Section 6(c)*

The rationales set forth in the *Restatement (Third)* for the special liability rules for drugs, vaccines, medical devices, and blood products do not sufficiently justify the ALI's failure to place these products within the alternative-safer-design analysis applicable to all other products. The *Restatement* gives the following reasons for the section 6(c) rule:

- (1) Plaintiffs have a negligence-based remedy for inadequate warnings.¹⁸¹
- (2) Plaintiffs have a strict-liability action for defects in manufacturing.¹⁸²
- (3) Patients have the protection of a learned intermediary—the prescribing physician—and so receive the information necessary to make an informed choice regarding the risks and benefits of prescription drugs.¹⁸³
- (4) Subjecting decisions about drug design to the section 2(b) defect analysis applicable to other products would hamper manufacturers' efforts to innovate and develop new medicines.¹⁸⁴
- (5) The FDA regulates drugs and vaccines for safety, effectiveness, and adequate labeling, rendering a stringent liability rule unnecessary.¹⁸⁵

180. *Id.* at 26, 28.

181. *See* RESTATEMENT (THIRD), *supra* note 1, § 6 cmt. d.

182. *See id.* cmt. c.

183. *See id.* cmt. b.

184. *See id.*

185. *See id.*

- (6) Increased exposure to liability would drive up the price of prescription drugs and make them less available to consumers.¹⁸⁶

None of these rationales justifies the rule of section 6(c). The availability of warning and manufacturing defect remedies is irrelevant to whether there should be a design-defect remedy. Although plaintiffs frequently plead all three theories, there are many cases in which the plaintiff can present a colorable design-defect claim, but has no evidence of a manufacturing defect or warning defect. For no other kind of product is it suggested that the availability of a warning claim makes the design-defect claim superfluous. No reasoning is offered for this radical departure from the general rule that products-liability law recognizes three distinct claims for warning defect, manufacturing defect, and design defect.

The advice of a learned intermediary undoubtedly is helpful in ensuring that patients are informed of the risks and benefits of taking prescription drugs. Moreover, the manner of use may be controlled through the prescription requirements imposed by the FDA.¹⁸⁷ Manufacturers' warnings and instructions to prescribing physicians properly are considered in determining the foreseeable uses and conditions of use of the product. However, physicians do not make design choices; they select from among products available in the market. The designer should no more be freed from its duty to market safe products by the existence of an intermediary physician than a manufacturer of industrial equipment should be relieved of the duty to include safety devices merely because employers are obligated by law to provide a safe workplace.¹⁸⁸

The FDA regulation defense is superficially appealing, but ultimately unsatisfactory. The FDA does not claim to review products for optimal design. It explains its review process as follows: "We assemble a team . . . to review the company's data and proposed use for the drug. If the drug is effective and we are convinced its health benefits outweigh its risks,

186. *See id.*

187. Possible regulations include the requirement that some drugs be prescribed only by physicians with special training and the approval of drugs only for certain uses. *See* Margaret Gilhooly, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 945 (1999).

188. *See* *Perez v. Wyeth Lab.*, 734 A.2d 1245, 1247 (1999) (imposing a duty on the defendant drug manufacturer adequately to inform users of prescription drugs regarding risks where there is direct-to-consumer advertising). The court noted that manufacturers may be held responsible even where others have played intervening roles; for example, a manufacturer may be liable for failing to include safety devices on machinery despite its expectation that the employer who purchased the machinery would install the devices. *See id.* at 1261 (citing *Bexiga v. Havar Mfg. Corp.*, 290 A.2d 281 (1972)).

we approve it for sale.”¹⁸⁹ FDA review thus asks less of drug and medical device manufacturers than the common law of products liability asks of other kinds of manufacturers.

It is therefore unsurprising that courts traditionally have rejected regulatory-compliance defenses, reasoning that meeting regulatory standards may not constitute reasonable care under the circumstances.¹⁹⁰ The defense is inconsistent with the general rule stated in section 4 of the *Restatement (Third)* that compliance with product-safety statutes and administrative regulations, while suggestive of reasonable care, is not dispositive.¹⁹¹ Section 4 reflects the traditional common-law tort doctrine that administrative codes set *minimum* requirements; reasonable care may require more. This is a prudent approach.

As Teresa Moran Schwartz has observed, in an era of constrained government resources, there may be more reason than ever to reject the regulatory-compliance defense.¹⁹² Products-liability actions can enforce regulatory standards effectively and may be more efficient than the cumbersome process of administrative rulemaking, which is so slow that government standards frequently become outdated.¹⁹³ In an environment that oscillates between fear of overregulation and demands for stricter controls—an environment characterized by budget pressures and frequent changes in political winds—the burden of persuasion falls on those who would have the courts depart from the prevailing rule that regulatory standards are relevant evidence, but not definitive statements, of what constitutes reasonable care in product design.

Nor should FDA approval of a medical product be viewed as a guarantee of the product's safety. Although Congress has expanded the FDA's function from policeman to gatekeeper,¹⁹⁴ it is by design a passive

189. CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., 1998 REPORT TO THE NATION: IMPROVING HUMAN HEALTH THROUGH HUMAN DRUGS 1 (1999).

190. See RESTATEMENT (SECOND), *supra* note 4, § 288C (citing decisions holding that compliance with a legislative enactment or administrative regulation does not preclude a finding of negligence where a reasonable person would have taken additional precautions); cf. N.J. STAT. ANN. § 2A:58C-4 (West 1999) (providing that in failure-to-warn suits, an FDA-approved warning carries a rebuttable presumption of adequacy).

191. RESTATEMENT (THIRD), *supra* note 1, § 4.

192. See Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431, 443-47 (1997).

193. See *id.* at 444-45.

194. See Merrill, *supra* note 22, at 1819-20. A legislative change in 1962 converted what had been a notification system (permitting marketing unless the FDA acted within 180 days) to a gatekeeping system in which the maker was obliged to wait for the agency to affirm safety and effectiveness. “The agency was empowered to require premarket approval for certain devices; however, Congress limited this form of control to products that were life-sustaining or presented significant risks to patients.” *Id.* at 1800. The FDA's review of new products remains limited by manpower constraints, budget constraints, and design. In 1993, the FDA Committee for Clinical Review reported “certain patterns of deficiencies in the design, conduct, and analysis of clinical

agency, not an initiator. The FDA reviews applications for premarket approval of new drugs and devices, but it does not conduct research or development. The tragedy of the hemophiliacs demonstrates the limitations inherent in this structure.¹⁹⁵

The tort system can encourage FDA regulatory vigor and competence. The FDA's proposed regulations to stem tobacco use by children and adolescents,¹⁹⁶ for example, were promulgated after states pursued tort actions to recover from the tobacco companies Medicaid money spent on smoking-related illnesses.¹⁹⁷ Information discovered in litigation (such as the tobacco companies' manipulation of nicotine levels in cigarettes and their knowledge of the addictiveness of nicotine), in addition to spurring the FDA to action, has been a powerful force in changing public attitudes about the risks of smoking and the culpability of the tobacco companies. Pictures of smokers' graveyards appear on roadside billboards, which until recently were graced by nubile couples cavorting in crystal waters and seeking cigarettes' promise of smooth satisfaction.¹⁹⁸

The regulatory-compliance defense is undermined further by the recognition that the decisions of courts can function in a way complementary to the regulatory function of administrative agencies. Tort litigation has a democratizing function. It not only can compel disclosure of policy-relevant information, but also may help inform regulators of evolving community standards and values. The focus of legal reform therefore should be not on substituting agency regulation for regulation by the tort liability system, but on determining how tort law and agency regulation can best complement one another to manage the burdens and benefits presented by technological change.¹⁹⁹ In this respect, it is helpful to recall that courts have a long tradition of borrowing legislative and

studies in sufficient numbers to suggest that these deficiencies represent a common problem" in reviewing pre-market approval applications. *Id.* at 1825.

195. A further problem with the regulatory-compliance defense is that rather than preventing litigation, the FDA-compliance defense may just shift the issues in drug injury litigation. *See Green, Statutory Compliance, supra* note 79, at 490-93, 508. Litigants will conduct inquiries into whether the manufacturer complied with FDA requirements for the investigation and marketing of the drug. *See id.* "The extensiveness of FDA regulations and the complexity of the pre-marketing testing process could transform that inquiry into a Serbian bog that would consume substantial resources." *Id.* at 508.

196. *See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents*, 60 Fed. Reg. 41,314 (1995) (to have been codified at 21 C.F.R. pts. 801, 803, 804, 897) (proposed Aug. 11, 1995). The measure has been stayed. *See Brown & Williamson Tobacco Co. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *cert. granted*, 119 S. Ct. 1495 (1999).

197. *See, e.g., Minnesota v. Philip Morris, Inc.*, No. C1-94-8565, 1998 Extra LEXIS 76 (D. Minn. Mar. 7, 1998).

198. The settlement agreement between Minnesota and Philip Morris mandates the removal of all tobacco billboards in the state and provides for more than \$100 million for smoking-cessation programs. *See Tobacco Companies To Pay Minnesota, Blue Cross \$6.6 Billion Plus Fees*, MEALEY'S LITIG. REP.: TOBACCO, May 21, 1998, at 5.

199. *See Mary L. Lyndon, Tort Law and Technology*, 12 YALE J. ON REG. 137 (1995).

regulatory standards to define standards of care for purposes of negligence claims.²⁰⁰ Administrative agencies also can borrow from the tort liability system: Their regulatory standards can be shaped by juries' expressions of social judgments about what conduct is and is not reasonable.

What of the argument that a tougher liability standard for drug manufacturers would hamper innovation in the drug market? It is argued, in support of section 6(c), that a more stringent liability rule would deter research and development of new and effective drugs; that manufacturers who did develop new drugs would test them longer, delaying their availability to consumers; and that beneficial drugs might be withdrawn from the market for fear of products-liability judgments.²⁰¹ However, prescription products already are subject to strict liability for manufacturing defects and negligence-based liability for failure to warn, and there is no suggestion in the *Restatement (Third)* that these liability rules intolerably hinder innovation. Moreover, even if increasing manufacturers' exposure to design-defect liability would result in some additional delay in bringing products to market, this would not necessarily be undesirable. The public might well have benefited from additional delay in bringing such products as factor concentrates for hemophiliacs, the Dalkon Shield,²⁰² and silicon breast implants²⁰³ to market, because the manufacturers might have developed a safer alternative design.

The accuracy of the objection that increased exposure to liability would hamper innovation is extremely difficult to gauge. Reliable data to explain the motivations of manufacturers, their behavior, and the consequences are largely unavailable.²⁰⁴ A RAND Corporation study, finding little evidence of a large effect of tort litigation on innovation, concluded that "liability is unlikely to deter efforts to develop a drug that offers a major breakthrough and the promise of huge profits," but that "[l]iability concerns may deter efforts to develop more modest drugs."²⁰⁵

200. See Schwartz, *supra* note 193, at 431; see also *Alloway v. Bradlees, Inc.*, 723 A.2d 960, 966-69 (N.J. 1999) (discussing the relevance of federal safety standards in determining the duty of care of a general contractor in preventing worksite injuries).

201. See Green, *Statutory Compliance*, *supra* note 79, at 466-67.

202. See generally *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (9th Cir. 1985) (involving a design-defect claim against the makers of the Dalkon Shield intrauterine device).

203. See MARCIA ANGELL, *SCIENCE ON TRIAL* 42-44 (1996) (describing safety-enhancing innovations in breast-implant design following the introduction of the first implants by Dow Corning).

204. See Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1288 (1992) ("In short, our society has been unable to produce research that is even minimally adequate to answer our most basic questions about the behavior of the civil justice system.").

205. MICHAEL D. GREEN, *BENEDICTIN AND BIRTH DEFECTS* 340 (1996) (citing STEVEN GARBER, *PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICAL AND MEDICAL DEVICES* 166, 174 (1993)).

The Reporter's note to section 6 cites no empirical evidence to bolster its assertion that design-defect liability for drugs would drive drug prices unacceptably high.²⁰⁶ The only support offered is a parenthetical citation to the *Brown* decision. The Reporters' failure to explain why the cost of injuries from defectively designed drugs and medical devices should be borne by the injured rather than the designer and manufacturer shows just how far we have strayed from the consumer-oriented days of strict products-liability law.²⁰⁷ The increased-cost argument resonates strongly in the current climate, but it is important to note that the fear of excessive costs is predicated on the notion that products-liability law is unpredictable. Because product manufacturers face great uncertainty in the tort system and the possibility of crippling jury awards, it is argued, they will be excessively cautious, with the result that the rate at which drugs are brought to market will be slowed and their price increased. This argument fails once we abandon the sometimes-confused liability regime of the section 402(A) era and adopt the more predictable alternative-safer-design test of section 2(b).

In summary, none of the rationales set forth in the *Restatement (Third)* justifies the bifurcation of products-liability law and the near-immunity from liability granted to makers of prescription drugs and other medical products. To the contrary, there are many reasons why meaningful design-defect review is desirable for such products. The deterrent and expressive functions of the tort system may help bring the values of the community to the minds of designers and regulators. Furthermore, courts, which act on a case-by-case basis, are also much more likely than legislatures to be able to measure accurately a product's benefits, risks, and alternatives. Courts also are better suited than legislatures to determine whether the dangers of a particular prescription drug or medical device are "unavoidable"—that is, not susceptible of design improvements. But under section 6(c)'s rule, none of these benefits of judicial review of medical product designs will be reaped.

CONCLUSION

The *Restatement (Third)* correctly restates the law of products liability in the alternative-safer-design test of section 2(b). In design-defect cases, it is generally a negligence standard, not a strict-liability rule, that determines whether a product is defective. That fault-based standard, the distilled

206. See RESTATEMENT (THIRD), *supra* note 1, § 6 cmt. b Reporter's note.

207. See James A. Henderson, Jr. & Theodore Eisenberg, *The Quiet Revolution in Products Liability: An Empirical Study of Legal Change*, 37 UCLA L. REV. 479 (1990) (describing the broad trends of judicial retrenchment, declining plaintiff success, and reduced awards in products-liability cases).

expression of thirty years of design-defect litigation, should be applied equally to medical products. The ALI should eliminate the special liability rules for drugs, medical devices, vaccines, and blood products set forth in sections 6(c) and 19(c). Drawing medical products into the fold of section 2 would resolve the doctrinal conflicts that have confused courts and legislatures and obstructed justice for persons such as the hemophiliacs who suffered reasonably preventable harms from medical products.

Section 6(c) casts aside the alternative-safer-design test for drugs and medical devices and instead urges courts to ask whether the product has a net benefit for any class of user. Among the rationales for this rule is the idea that medical products are of special importance because of their lifesaving qualities. But it is not the social utility of a product that is at issue in traditional fault-based design-defect analysis; it is the designer's failure to adopt an available, practical, and safer design. Because alternative-design analysis will be increasingly viable for prescription drugs and medical devices as medical science advances, it is important for the ALI to close the gap between the *Feldman-Kearl-Toner* line of cases and the *Brown* line by establishing a clear negligence standard applicable to all products.

The pharmaceutical industry, like every regulated industry, seeks freedom from liability and regulatory constraints in order to pursue unfettered innovation. Its plea for freedom often falls on sympathetic ears, both in the legislatures and among consumers.²⁰⁸ But the price of freedom is responsibility. The process of invention is policed, but not controlled, by regulatory agencies. The general thrust of the *Restatement* of products-liability law has been to place primary responsibility for product safety on the designer, not the regulator or the reseller. Arguments for immunity or near-immunity from design-defect liability cut against that trend. The law should encourage product designers to ask not only how to make a product, but also whether to make it, and why. The designer should consider the full range of design considerations.²⁰⁹ The process of selecting a design should be informed by the knowledge that the designer someday may have to justify the particular balance it chose between risk and utility. Such thoughtful consideration of the need to justify design choices ultimately will result in better, safer products.

208. See, e.g., STEVEN EPSTEIN, *IMPURE SCIENCE* 339 (1996) (detailing the impact that AIDS activists have had on the FDA drug-approval process, including expanded access to experimental therapies and accelerated approval).

209. Cf. Owen, *supra* note 47, at 754 ("[T]he goal of both design engineers and the law should be to promote in products an ideal *balance* of product usefulness, cost, and safety.").

